PSJ3

Exhibit 674D

TABLE 1, CONTINUED.

STATE	POLICY TYPE	YEAR ADOPTED	TITLE OR REFERENCE NUMBER
Missouri	Guideline	2001	Palliative Care Guidelines
Missouri	Guideline	2001	Model Guidelines for the Use of Controlled Substances for the Treatment of Pain
Montana	Guideline	1996	Statement on the Use of Controlled Substances in the Treatment of Intractable Pain, Guidelines for Prescribing Opioid Analgesics for Chronic Pain
Nebraska	Guideline	1999	Guidelines for the Use of Controlled Substances for the Treatment of Pain
Nevada	Regulation	1996	Nev. Admin. Code 630.255
Nevada	Regulation	1999	Nev. Admin. Code 630.020
Nevada	Regulation	1999	Nev. Admin. Code 630.193
Nevada	Regulation	1999	Nev. Admin. Code 630.195
Nevada	Regulation	1999	Nev. Admin. Code 630.197
Nevada	Regulation	1999	Nev. Admin. Code 630.230
Nevada	Regulation	2000	Nev. Admin. Code 630.187
Nevada	Regulation	2000	Nev. Admin. Code 630.230
New Hampshire	Guideline	2000	Guidelines for the Use of Controlled Substances in the Management of Chronic Pain
New Jersey	Regulation	1997	N.J. Admin. Code. § 13:35-7.6
New Mexico	Guideline	1996	Guidelines on Prescribing for Pain
New York	Guideline	2000	Policy Statement for the Use of Controlled Substances for the Treatment of Pain
North Carolina	Policy Statement	1996	Management of Chronic Non-Malignant Pain
North Carolina	Policy Statement	1999	End-of-Life Responsibilities and Palliative Care
North Carolina	Policy Statement	1999	Joint Statement on Pain Management in End-of-Life Care
Ohio	Policy Statement	1994	Scheduled Drug Therapy Including Narcotics for Chronic Benign Pain
Ohio	Policy Statement	1996	Scheduled Drug Therapy Including Narcotics for Chronic Benign Pain (Revised)
Ohio	Regulation	1998	Ohio Admin. Code Ann. 4731-21-01-06
Oklahoma	Guideline	1994	Guidelines for Prescribing Controlled Substances for Intractable Pain
Oklahoma	Regulation	1999	Okla. Admin. Code 435:10-7-11
Oregon	Policy Statement	1991	Statement of Philosophy: Appropriate Prescribing of Controlled Substances
Oregon	Policy Statement	1995	Pain Management on Acute Conditions and Terminal Illness
Oregon	Regulation	1996	Or. Admin. R. 847-015-0030
Oregon	Policy Statement	1999	Current Philosophy on Pain Management
Pennsylvania	Regulation	1985	49 Pa. Code § 16.92
Pennsylvania	Guideline	1998	Guidelines for the Use of Controlled Substances in the Treatment of Pain

Continued on next page

TABLE 1, CONTINUED.

STATE	POLICY TYPE	YEAR ADOPTED	TITLE OR REFERENCE NUMBER
Rhode Island	Guideline	1995	Guidelines for Long Term Pain Management
South Carolina	Guideline	1999	Guidelines for the Use of Controlled Substances for the Treatment of Pain
South Dakota	Guideline	1999	Model Guidelines for the Use of Controlled Substances for the Treatment of Pain
Tennessee	Policy Statement	1995	Management of Prescribing with Emphasis on Addictive or Dependence-Producing Drugs
Tennessee	Regulation	1999	Tenn. Comp. R. & Regs. R. 0880-2-.14
Texas	Policy Statement	1993	Pain Control and the Texas State Board of Medical Examiners
Texas	Regulation	1995	22 Tex. Admin. Code § 170.1-170.3
Utah	Policy Statement	1992	Prescribing Controlled Substances for Cancer Pain: Position Paper of the Utah Division of Occupational and Professional Licensing
Utah	Guideline	1999	Model Guidelines for the Use of Controlled Substances for the Treatment of Pain
Vermont	Guideline	1996	Report of the Prescribing Practices Committee
Virginia	Guideline	1998	Guidelines for the Use of Opioids in the Management of Chronic, Non-Cancer Pain
Washington	Policy Statement	1987	Bulletin to Physicians Issued by the Medical Disciplinary Board
Washington	Policy Statement	1989	Policy Statement on Chronic Pain Issued by the Medical Disciplinary Board
Washington	Policy Statement	1992	Guidelines on Opiate Usage
Washington	Policy Statement	1996	Guidelines for the Management of Pain
Washington	Regulation	1999	Wash. Admin. Code § 246-919-800
West Virginia	Policy Statement	1997	Positive Statement on the Use of Opioids in the Treatment of Chronic Non-Malignant Pain
West Virginia	Policy Statement	2001	Joint Policy Statement on Pain Management at the End of Life
Wyoming	Policy Statement	1996	Letter to Wyoming Physicians

agement (Criteria 1 through 8), and (2) "negative" criteria, which recognize policy language that has the potential to impede pain management (Criteria 9 through 17). Policy language that was identified by the policy analysts as meeting one or more criteria served as the "data" for this research.

"Positive" criteria identify policies that recognize fundamental legal and medical principles (i.e., that opioids as controlled substances are necessary for public health, and that pain management and use of opioids are part of legitimate medical practice). They also identify policy provisions that encourage pain management and address fears of regulatory scrutiny. In addition, these criteria will show whether policies correct outdated notions about opioids that can interfere with pain management (e.g., that the amount prescribed is *not* sufficient to determine the legitimacy of prescribing, and that physical dependence and tolerance are *not* synonymous with addiction). An "other" category identifies policy provisions not specific to one of the other positive criteria but that may enhance pain management.

The "negative" criteria are used to identify policy provisions that are outdated or would be otherwise inappropriate in a balanced policy governing the medical use of controlled substances and the treatment of pain. These criteria identify

Table 2. Criteria Used to Evaluate State Medical Board Policies.

Positive criteria: Criteria that identify policy language with the potential to enhance pain management

1. Controlled substances are recognized as necessary for the public health
2. Pain management is recognized as part of general medical practice
3. Medical use of opioids is recognized as legitimate professional practice
4. Pain management is encouraged
5. Practitioners' concerns about regulatory scrutiny are addressed
6. Prescription amount alone is recognized as insufficient to determine the legitimacy of prescribing
7. Physical dependence or analgesic tolerance is not confused with addiction
8. Other provisions that may enhance pain management

Negative criteria: Criteria that identify policy language with the potential to impede pain management

9. Opioids are implied to be a last resort
10. Medical use of opioids is implied to be outside of legitimate professional practice
11. The belief that opioids hasten death is perpetuated
12. Physical dependence or analgesic tolerance is confused with addiction
13. Medical decisions are restricted
    - 13.1 Restrictions based on patient characteristics
    - 13.2 Mandated consultation
    - 13.3 Restrictions regarding quantity prescribed or dispensed
14. Length of prescription validity is restricted
15. Practitioners are required to use government-issued prescription forms
16. Other provisions that may impede pain management
17. Provisions that are ambiguous

language that suggests that opioid use is outside of ordinary medical practice, that opioids are to be used only as a last resort, or that their therapeutic use hastens death. This category also identifies provisions that confuse physical dependence and tolerance with addiction, or that restrict decisions that are medical in nature, such as preventing prescribing opioids to patients with pain who have a history of substance abuse, mandating consultation for every patient who receives opioids, or specifying a limit to the quantity of drug that can be prescribed at one time. Negative criteria also identify policies that unrealistically limit the period for which a prescription is valid after being issued, or that require physicians to use only special government-issued prescription forms. "Other" and "ambiguous" categories identify requirements that may interfere with pain management, but do not relate to the aforementioned negative criteria.

A provision was judged to satisfy a criterion on the basis of the policy's plain language, not by its implication or intent. For example, a guideline adopted by the Idaho State Board of Medicine in 1995, entitled "Prescribing Opioids for Chronic Pain,"[12] may have been intended to encourage physicians to treat pain effectively. However, this policy did not satisfy Criterion 4 because it did not contain an explicit statement encouraging pain management. In addition, if a provision appeared more than once in the same policy, it was counted only once. However, provisions satisfying Criteria 8, 16, and 17 could be counted more than once if they represented different types of policy content.

Using these criteria, the PPSG had previously evaluated 61 percent of the medical board policies; these policies were not reviewed again. The team of policy analysts met to compare their evaluations and identify lack of agreement or discrepancies. The initial agreement rate was 93 percent. The researchers discussed and resolved each discrepancy, which usually resulted from oversights or minor differences in interpretation. Complete consensus was achieved regarding the evaluation of each policy. The results of the evaluation were entered into an Excel database.

Statistical analysis

Frequency distributions were calculated for the number of positive and negative provisions found in each policy, as well as the total for each criterion. The frequencies had statistically nonnormal distributions, requiring the use of a nonparametric method for independent samples. Descriptive statistics were used to compare the Model Guidelines to subsequent policies (Research Aim 1). The chi-square test of association was used to compare policies that were developed prior to the Model Guidelines to those adopted subsequently (Research Aim 2), as well as to compare the content across types of policies (i.e., regulations, guidelines, and policy statements) (Research Aim 3).

Results

Policy provisions

The total sample of state medical board policies was seventy-nine, comprising twenty-six regulations, thirty-two guidelines, and twenty-one policy statements. Forty-one states were represented, with a mean of almost two policies per state (the range was one to eight policies). Forty-three policies (54.4 percent) predated the approval of the FSMB's Model Guidelines (called "pre-Model" policies), while thirty-six (45.6 percent) were adopted subsequently (called "post-Model" policies).

The frequency of positive and negative provisions varied for each policy. Eleven policies (13.9 percent) contained no positive provisions, twenty-seven (34.2 percent) contained one or two positive provisions, and forty-one (51.9 percent) contained between three and eight positive provisions. We found that thirty-nine policies (49.4 percent) had no negative provisions, twenty-eight (35.4 percent) had one or two, and twelve (15.2 percent) had three to five. In relation to individual criterion, no medical board policies contained language that recognized controlled substances as necessary for public health (Criterion 1), perpetuated the belief that opioids hasten death (Criterion 11), restricted the length of prescription validity (Criterion 14), or required the use of government-issued prescription forms (Criterion 15). Table 3 contains the number and frequency with which each criterion was identified in the total sample of policies, the Model Guidelines, pre-Model policies, and post-Model policies.

Research Aim 1: Comparison of the Model Guidelines to subsequent policies

It is important to begin with an evaluation of the Model Guidelines. The Model Guidelines met Criteria 2 through 8, and had no provisions meeting Criteria 9 through 17 (see Table 3). Alternatively, over 50 percent of post-Model policies contained provisions that met Criteria 2 through 7, and 47 percent met Criterion 8. Only a few post-Model policies contained negative provisions. When comparing all post-Model policies, guidelines were more likely than regulations or policy statements to contain positive provisions ($\chi^2(6) = 12.815$, $p < 0.046$), such as recognizing the use of opioids as legitimate professional practice (Criterion 3) ($\chi^2(2) = 8.230$, $p < 0.016$), encouraging pain management (Criterion 4) ($\chi^2(2) = 13.936$, $p < 0.001$), and not confusing addiction with either physical dependence or tolerance (Criterion 7) ($\chi^2(2) = 7.599$, $p < 0.022$).

Research Aim 2: Comparison of policies before and after the Model Guidelines

These analyses compared pre-Model and post-Model policies to identify differences in the number of provisions that have a potential to affect pain management, and to better

Table 3. Criteria Identified in Policies.

Criterion	Total Policies [#(%)] $N = 79$	Model Guidelines	Pre-Model Policies [#(%)] $N = 43$	Post-Model Policies [#(%)] $N = 36$
Criterion 1	0 (0)	No	None	None
Criterion 2	36 (45.6)	Yes	13 (30.2)	23 (63.9)
Criterion 3	43 (54.4)	Yes	22 (51.2)	21 (58.3)
Criterion 4	33 (41.8)	Yes	11 (25.6)	22 (61.1)
Criterion 5	39 (49.4)	Yes	18 (41.9)	21 (58.3)
Criterion 6	31 (39.2)	Yes	11 (25.6)	20 (55.6)
Criterion 7	32 (40.5)	Yes	10 (23.3)	22 (61.1)
Criterion 8	26 (32.9)	Yes	9 (20.9)	17 (47.2)
Criterion 9	31 (39.2)	No	24 (55.8)	7 (19.4)
Criterion 10	11 (13.0)	No	6 (14.0)	5 (13.9)
Criterion 11	0 (0)	No	0 (0)	0 (0)
Criterion 12	2 (2.5)	No	2 (4.7)	0 (0)
Criterion 13.1	1 (1.3)	No	1 (2.3)	0 (0)
Criterion 13.2	14 (17.7)	No	11 (25.6)	3 (8.3)
Criterion 13.3	2 (2.5)	No	1 (2.3)	1 (2.8)
Criterion 14	0 (0)	No	0 (0)	0 (0)
Criterion 15	0 (0)	No	0 (0)	0 (0)
Criterion 16	10 (12.7)	No	9 (20.9)	1 (2.8)
Criterion 17	7 (8.9)	No	3 (7.0)	4 (11.1)

understand how the Model Guidelines may have influenced state medical board policy development.

Differences in total positive and negative provisions

Pre-Model and post-Model policies were first compared according to their total number of positive and negative provisions. Post-Model policies had significantly more positive provisions ($\chi^2(3) = 14.796$, $p < 0.002$), and were more likely to have no negative provisions ($\chi^2(2) = 24.602$, $p < 0.0001$).

The types of pre- and post-Model policies (regulations, guidelines, and policy statements) also were compared according to their total number of provisions. Post-Model regulations were significantly more likely than pre-Model regulations to contain no negative provisions ($\chi^2(2) = 7.317$, $p < 0.026$). Post-Model guidelines had significantly more positive provisions ($\chi^2(3) = 14.823$, $p < 0.002$), and no negative provisions ($\chi^2(2) = 12.053$, $p < 0.002$), when compared to pre-Model guidelines. There were no significant differences between pre- and post-Model policy statements.

Changes in the number of individual provisions

We compared pre- and post-Model policies according to the frequency of individual positive and negative provisions. Pre-Model policies were more likely to contain negative provisions that could restrict prescribing or medical decision-making, including language that implied that opioids are a last resort for pain treatment (Criterion 9) ($\chi^2(1) = 10.871$, $p < 0.001$), mandated consultation (Criterion 13.2) ($\chi^2(1) = 3.998$, $p < 0.046$), and created other potential impediments to pain management (Criterion 16) ($\chi^2(2) = 5.941$, $p < 0.05$). Post-Model policies were significantly more likely to include positive provisions that recognized pain management as part of medical practice (Criterion 2) ($\chi^2(1) = 8.949$, $p < 0.003$), encouraged pain management (Criterion 4) ($\chi^2(1) = 10.170$, $p < 0.001$), recognized amount or duration of prescribing as insufficient to determine legitimacy of prescribing (Criterion 6) ($\chi^2(1) = 7.384$, $p < 0.007$), and did not confuse addiction with physical dependence or tolerance (Criterion 7) ($\chi^2(1) = 11.652$, $p < 0.001$).

Regulations, guidelines, and policy statements were examined separately to determine how the content of each policy type varied after publication of the Model Guidelines. Post-Model guidelines were significantly more likely to include the following positive provisions: recognizing pain management as part of medical practice (Criterion 2) ($\chi^2(1) = 7.429$, $p < 0.006$), encouraging pain management (Criterion 4) ($\chi^2(1) = 11.888$, $p < 0.001$), recognizing amount or duration of prescribing as insufficient to determine legitimacy (Criterion 6) ($\chi^2(1) = 5.427$, $p < 0.020$), and not confusing addiction with physical dependence or tolerance (Criterion 7) ($\chi^2(1) = 8.016$, $p < 0.005$). In addition, post-Model guidelines were less likely to include language that implied that opioids are a last resort for pain treatment (Criterion 9) ($\chi^2(1) = 6.419$, $p < 0.011$) or mandated consultation (Criterion 13.2) ($\chi^2(1) = 8.880$, $p < 0.003$). Post-Model regulations were more likely to clarify that addiction is not synonymous with physical dependence or tolerance (Criterion 7) ($\chi^2(1) = 7.287$, $p < 0.007$), while post-Model policy statements were more likely to include language that encouraged pain management (Criterion 4) ($\chi^2(1) = 7.765$, $p < 0.005$). Table 4 contains a summary of the statistically significant results for Aim 2.

Table 4. Summary of Results for Research Aim 2.

	Post-Model vs. Pre-Model Policies			
Provisions	All Policies	Regulations	Guidelines	Policy Statements
Total positive provisions	(+) $p < 0.002$	ns	(+) $p < 0.002$	ns
Total negative provisions	(0) $p < 0.0001$	(0) $p < 0.026$	(0) $p < 0.002$	ns
Criteria				
2	(+) $p < 0.003$	ns	(+) $p < 0.006$	ns
4	(+) $p < 0.001$	ns	(+) $p < 0.001$	(+) $p < 0.005$
6	(+) $p < 0.007$	ns	(+) $p < 0.020$	ns
7	(+) $p < 0.001$	(+) $p < 0.007$	(+) $p < 0.005$	ns
9	**$p < 0.001$**	ns	(-) $p < 0.011$	ns
13.2	**$p < 0.046$**	ns	(-) $p < 0.003$	ns
16	**$p < 0.050$**	ns	ns	ns

(+) = more provisions in post-Model policies; (-) = fewer provisions in post-Model policies; (0) = no provisions in post-Model policies; ns = not significant. The bolded significant levels indicate that the pre-Model policies, rather than post-Model policies, were more likely to contain language that met negative criteria.

Research Aim 3: Comparison of policy types

Analyses were conducted to determine the extent that the frequency of provisions varied according to type of policy, independent of the year they were adopted. For this research aim, guidelines and policy statements were combined, because neither policy has the force of law, and were then compared to regulations. The comparison between the two groups revealed no significant difference in the total number of positive provisions; however, regulations had more negative provisions ($\chi^2(2) = 6.544, p < 0.038$). Regulations were significantly more likely to imply that the medical use of opioids is outside legitimate professional practice (Criterion 10) ($\chi^2(1) = 13.844, p < .0001$), and have more ambiguous language (Criterion 17) ($\chi^2(1) = 9.699, p < 0.002$). Guidelines and policy statements were significantly more likely than regulations to address physicians' concerns about regulatory scrutiny (Criterion 5) ($\chi^2(1) = 5.363, p < 0.021$).

Discussion

This study suggests that, since their publication in May 1998, the FSMB's Model Guidelines have positively influenced many state medical board policies addressing pain management — twenty-two states have adopted the Model Guidelines either in whole or in part. More than half of the post-Model policies contained language similar to the Model Guidelines, recognizing that pain management is part of medical practice, encouraging pain management, and using correct definitions of addiction-related terms. In addition, most post-Model policies did not include language that could unduly restrict physician decision-making, medical practice, and patient care.

The Model Guidelines appeared to have different effects on the content of regulations, guidelines, and policy statements. State medical board guidelines evidenced the greatest change in content after the Model Guidelines were published, both in terms of more positive provisions and fewer negative provisions. Although regulations adopted after the Model Guidelines were less likely to have potentially restrictive language, policy statements showed no significant changes over time (despite a moderate trend toward fewer negative provisions, $p = 0.062$). When examining only those policies developed after the Model Guidelines, we found that guidelines were more likely than either regulations or policy statements to include language that has the potential to enhance pain management. As a result, the Model Guidelines appear to have had the most influence on the content of medical board guidelines. Overall, however, post-Model policies showed notable improvement over policies adopted prior to the Model Guidelines (as demonstrated in Table 3).

Despite these improvements in pain management policies, it is evident that some boards developed policies independent of the Model Guidelines. These policies contained provisions that had the potential to impede pain management, indeed to regulate it strictly. A small proportion of the policies adopted after the Model Guidelines suggested that the prescribing of controlled substances for the treatment of pain is a last resort and not within the ordinary practice of medicine, and required consultation with a specialist for all physicians with patients who receive opioids. The prevalence of negative provisions like these was more frequent in regulations. Such provisions appear to restrict physicians' flexibility in the management of patients with pain, regulating rather than guiding pain management and medical practice with controlled substances, and doing so more strictly than federal law and the policies in most other states. In contrast, the Model Guidelines recommend flexibility by stating that the physician will not be disciplined for failing to follow the guidelines if good cause can be shown.[13]

The FSMB developed the Model Guidelines to encourage effective pain management and to view such practice as within the bounds of legitimate professional practice, to serve as an alternative to legislative action, and to achieve a greater degree of consistency among the states with respect to pain and controlled substances policy.[14] The evidence presented here indicates that these goals are being achieved in many, if not all, states.

Another principal aim of the Model Guidelines was to address directly physicians' concerns about regulatory scrutiny by clarifying the policy of medical boards, as this was recognized as a significant barrier to the adequate treatment of pain.[15] However, when pre- and post-Model medical board policies were compared, we found no difference in the extent to which they addressed practitioners' concerns about regulatory scrutiny (Criterion 5; $p = 0.145$). This nonsignificant result can be attributed, at least in part, to the influence and timing of the 1994 California Medical Board policy, Guidelines for Prescribing Controlled Substances for Intractable Pain.[16] Of the twelve state medical board pain management policies adopted before California's 1994 guidelines, only one (Minnesota's) contained a statement aimed at reducing physicians' fears of unwarranted sanctions for prescribing controlled substances. Indeed, additional analyses found that state medical board pain policies adopted within a few years of the 1994 California guidelines were more likely to contain language that met Criterion 5. Although language from the Model Guidelines addressing regulatory scrutiny was based on the 1994 California policy, the California guidelines had already substantially influenced state policy development in the mid-1990s.

Criterion 1 was not identified in these analyses; it was developed to evaluate federal and state laws affecting pain management.[17] Typically, such policy language is designed for controlled substances statutes or regulations, rather than medical practice policy, and is based on a different model, the Uniform Controlled Substances Act.[18] It is not surprising, therefore, that state medical board policies did not contain

provisions satisfying this criterion. Although language that perpetuates the belief that opioids hasten death (Criterion 11), restricts length of prescription validity (Criterion 14), or requires the use of government-issued prescription forms (Criterion 15) was not found to exist in any medical board policies, such provisions do appear in controlled substances, medical practice, or other state statutes.[19]

Conclusions

Undertreatment of pain continues to be a serious problem due in part to barriers that are found in the language of some state medical board policies. For example, we found that many policies aimed at providing immunity to physicians for prescribing controlled substances for pain actually contained language that suggests that opioid analgesics are not part of generally accepted medical practice and are to be used as a treatment modality of last resort.

State medical boards have the authority to regulate medical practice; they have also evidenced a willingness to promulgate board policy that encourages treatment of pain and addresses some of the barriers to effective pain relief, such as physicians' concerns about being investigated for prescribing controlled substances. Based on our policy analysis, it is clear that greater uniformity in policy is being achieved, but complete consistency remains an elusive goal. Professional licensing boards are once again encouraged to review and update their policies, if they have not done so recently. Indeed, the Model Guidelines provide a carefully thought-out template for judicious prescribing for better pain management, while also requiring compliance with federal and state controlled substances laws and regulations. With increased misuse of opioid pain medications and associated media coverage, efforts to address drug abuse and diversion must not interfere with the use of these drugs for pain management.

Once a state board adopts balanced policy, it must be successfully implemented. This process is essential because it informs practitioners of the availability and messages of the board's policy. Such activities could involve the following three-tiered process:

- training of investigators about the current standards of pain management;
- disseminating the policy to licensees via the board's newsletter and website; and
- using radio and television to reach the general public.

For example, the North Carolina Board of Medical Examiners has used its newsletter to issue and discuss its policies, and has participated in television coverage to disseminate its message to a large audience.[20] The Maryland Board of Physician Quality Assurance created a videotape about "balance" that is viewed by each new licensee.[21] State medical boards also can sponsor workshops about pain management and board policy; the Minnesota State Board of Medical Practice has sponsored twelve such workshops. Activities like these can effectively communicate a positive attitude and policy toward pain management and can address directly physicians' concerns about regulatory scrutiny and, ultimately, improve patient care.

Acknowledgments

The research described in this article was supported by a grant from the Robert Wood Johnson Foundation.

References

1. W. Breitbart, M. Kaim, and B. Rosenfeld, "Clinicians' Perceptions of Barriers to Pain Management in AIDS," *Journal of Pain and Symptom Management*, 18, no. 3 (1999): 203–12; W. Breitbart et al., "Patient-Related Barriers to Pain Management in Ambulatory AIDS Patients," *Pain*, 76 (1998): 9–16; C.S. Cleeland, "Barriers to the Management of Cancer Pain," *Oncology*, suppl. (April 1987): 19–26; R.A. Drayer, J. Henderson, and M. Reidenberg, "Barriers to Better Pain Control in Hospitalized Patients," *Journal of Pain and Symptom Management*, 17, no. 6 (1999): 434–40; B.A. Ferrell, "Pain Evaluation and Management in the Nursing Home," *Annals of Internal Medicine*, 123, no. 9 (1995): 681–87; C.S. Hill, Jr., "The Barriers to Adequate Pain Management with Opioid Analgesics," *Seminars in Oncology*, 20, no. 2, suppl. 1 (1993): 1–5; D.E. Joranson, "Are Health-Care Reimbursement Policies a Barrier to Acute and Cancer Pain Management?," *Journal of Pain and Symptom Management*, 9, no. 4 (1994): 244–53, *available at* <http://www.medsch.wisc.edu/painpolicy/publicat/94jpsma.htm>; D.E. Joranson, "Regulatory Influence on Pain Management: Real or Imagined?," *Journal of Pharmaceutical Care in Pain and Symptom Control*, 1, no. 1 (1993): 113–18, *available at* <http://www.medsch.wisc.edu/painpolicy/publicat/93jpcpsc.htm>; F. Larue et al., "Oncologists and Primary Care Physicians' Attitudes Toward Pain Control and Morphine Prescribing in France," *Cancer*, 76, no. 11 (1995): 2375–82; M. McCaffery, "Pain Control: Barriers to the Use of Available Information," *Cancer*, 70, no. 5 (1992): 1438–49; B.A. Rich, "An Ethical Analysis of the Barriers to Effective Pain Management," *Cambridge Quarterly of Healthcare Ethics*, 9 (2000): 54–70; S.W. Tolle et al., "Family Reports of Barriers to Optimal Care of the Dying," *Nursing Research*, 49, no. 6 (2000): 310–17.

2. Cancer Pain Management Policy Review Group, *American Cancer Society Position Statement on Regulatory Barriers to Quality Cancer Pain Management* (Atlanta: American Cancer Society, 2001); J.D. Haddox and G.M. Aronoff, "Commentary: The Potential for Unintended Consequences from Public Policy Shifts in the Treatment of Pain," *Journal of Law, Medicine & Ethics*, 26, no. 4 (1998): 350–52; C.S. Hill, Jr., "The Negative Effect of Regulatory Agencies on Adequate Pain Control," *Primary Care in Cancer*, 11 (1989): 47–51; C.S. Hill, Jr., "The Negative Influence of Licensing and Disciplinary Boards and Drug Enforcement Agencies on Pain Treatment with Opioid Analgesics," *Journal of Pharmaceutical Care in Pain and Symptom Control*, 1, no. 1 (1993): 43–62; K.M. Foley and H. Gelband, eds., Institute of Medicine National Cancer Policy Board, *Improving Palliative Care for Cancer* (Washington, D.C.: National Academy Press, 2001), *available at* <http://www.nap.edu/catalog/10149.html>.

3. Washington State Medical Disciplinary Board, *Bulletin to*

Physicians: Chronic Pain (1987).

4. State of Washington Department of Health, *Policy Statement* (1989).

5. State of Washington Department of Health, *Policy Statement to the Washington State Medical Disciplinary Board: Guidelines for Opiate Usage* (1992): at 1.

6. State of Washington Department of Health, *Guidelines for Management of Pain* (1996), *available at* <http://www.medsch.wisc.edu/painpolicy/domestic/wambguid.htm>.

7. California Medical Board, "A Statement by the Medical Board," *Action Report*, 50 (1994): 4–5, *available at* <http://www.medsch.wisc.edu/painpolicy/domestic/cambstmt.htm>; California Medical Board, "Guideline for Prescribing Controlled Substances for Intractable Pain," *Action Report*, 51 (1994): 1, 8, *available at* <http://www.medsch.wisc.edu/painpolicy/domestic/cambguid.htm>; D.E. Joranson, "State Medical Board Guidelines for Treatment of Intractable Pain," *American Pain Society Bulletin*, 5, no. 3 (1995): 1–5, *available at* <http://www.medsch.wisc.edupain policy/publicat/95apssm.htm>.

8. Federation of State Medical Boards of the United States, *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* (Euless, Texas: Federation of State Medical Boards of the United States, 1998), *available through* <http://www.fsmb.org>.

9. Federation of State Medical Boards of the United States, *Position of the Federation of State Medical Boards in Support of Adoption of Pain Management Guidelines* (Euless, Texas: Federation of State Medical Boards of the United States, 2000), *available at* <http://www.medsch.wisc.edu/painpolicy/domestic/FSMBwp.htm>.

10. D.E. Joranson et al., *2001 Annual Review of State Pain Policies: A Question of Balance* (Madison: Pain & Policy Studies Group, University of Wisconsin Comprehensive Cancer Center, 2002): at 2, *available at* <http://www.medsch.wisc.edu/painpolicy/publicat/01annrev/contents.htm>.

11. D.E. Joranson et al., *Achieving Balance in Federal and State Pain Policy: A Guide to Evaluation* (Madison: Pain & Policy Studies Group, University of Wisconsin Comprehensive Cancer Center, 2000): at 13–17, *available at* <http://www.medsch.wisc.edu/painpolicy/eguide2000/index.html>.

12. Idaho State Board of Medicine, "Prescribing Opioids for Chronic Pain," *State Pamphlet* (March 1995), *available at* <http://www.medsch.wisc.edu/painpolicy/domestic/idmbguid.htm>.

13. See Federation of State Medical Boards, *supra* note 8, at 2.

14. House of Delegates of the Federation of State Medical Boards (May 1998).

15. See Federation of State Medical Boards, *supra* note 9.

16. See California Medical Board, *supra* note 7.

17. See Joranson et al., *supra* note 11, at 18.

18. National Conference of Commissioners on Uniform State Laws, Uniform Controlled Substances Act (of 1990); National Conference of Commissioners on Uniform State Laws, Uniform Controlled Substances Act (of 1994), *available at* <http://www.law.upenn.edu/bll/ulc/fnact99/1990s/ucsa94.pdf>.

19. See Joranson et al., *supra* note 11.

20. D.E. Joranson, A.M. Gilson, and J.A. Nischik, "North Carolina, Pain Management and End-of-Life Care: Communicating the Policy," *Federation Bulletin: Journal of Medical Licensure & Discipline*, 88, no. 3 (2002): 116–19, *available at* <http://www.medsch.wisc.edu/painpolicy/publicat/02fsmb/index.htm>.

21. *Maryland Board of Physician Quality Assurance: A Sense of Balance — Treating Chronic Pain*, produced by Maryland Public Television: Special Projects Unit, 20 min. (1998), videocassette.

Pain Management References

Okie, Susan, California Jury Finds Doctor Negligent in Managing Pain. *Washington Post.* June 15, 2001: A02

Crane, Mark. Treating Pain: Damned if you don't. *Medical Economics.* November 19, 2001:66-68.

Meisel, Alan, Snyder, Lois, Quill, Timothy. Seven Legal Barriers to End-of-Life Care. JAMA. 2000; 284(19):2495-2501

Steinhauser, Karen E., Nicholas A. Christakis, Elisabeth D. Clipp, et al. Factors Considered Important at the End of Life by Patients, Family, Physicians, and Other Care Providers. *JAMA.* 2000; 284(19): 2476-2482

Quill, Timothy. Death with Dignity. A Case of Individualized Decision-making. *NEJM.* 1991; 324:691-694

Quill, Timothy. Palliative Options of Last Resort. A Comparison of Voluntary Stopping of Eating and Drinking, Terminal Sedation, Physician-assisted Suicide and Voluntary Euthanasia. *JAMA.* 1995; 278(23): 2099-2104.

SUPPORT. A Controlled Trial to Improve Care for Seriously Ill Hospitalized Patients. The Study to Understand Prognosis and Preferences for Outcomes and Risks of Treatments (SUPPORT). *JAMA.* 1995; 274(20):1591-1598.

Byock, Ira, Arthur Caplan, and Lois Snyder. Beyond Symptom Management: Physician Roles and Responsibility in Palliative Care. In *Physician's Guide to End-of-Life Care,* ed Lois Snyder and Timothy Quill. Philadelphia: American College of Physicians. 2001; 56-71.

American College of Physicians. Ethics Manual. 4th ed. *Ann Int Med.* 1998;128:576-594

The Oath of Hippocrates. In *The Physician's Creed: an anthology of medical prayers, oaths, and codes of ethics written and recited by medical practitioners through the ages.* 13-14. Springfield, ILL. : Charles C. Thomas, 1973.

Institute of Medicine. *Approaching Death: Improving Care at the End of Life.* Washington, DC: National Academy Press. 1997.

CFR, Title 21, Part 1306.04a

21 USC 824, referencing 21 USC 823

Pain and Policy Studies Group. *Achieving Balance in Federal and State Pain Policy.* 2000. www.medsch.wisc.edu/painpolicy

Uniform Controlled Substances Act 195.101 R.S. Mo

DEA Physician's Manual. March 1990. 21

Glucksberg v. Washington, 117 S.Ct. 2258 (1997) and Quill v. Vacco, 117 S.Ct. 2293 (1997).

The Oregon Death With Dignity Act. Ballot Measure #16 (1994); Revised Statute 127.800-.995 (1995).

Editorial. Kill the Pain, not the Patient. *The Oregonian.* July 1, 1999.

Annas, G. Death by Prescription—The Oregon Initiative. *NEJM.* 1994; 331(18):1240-1243.

Orentlicher, D and Arthur Caplan. The Pain Relief Promotion Act of 1999. A Serious Threat to Palliative Care. *JAMA.*2000; 283(2):255-258

Walsh, B. Side Effect of Suicide Bill Criticized. *The Times Picayune.* New Orleans, LA. September 21, 2000.

USA Today. Ashcroft Allows Agents to go After Suicide Assistance. November 6, 2001. www.usatoday.com/news/washdc/nov01/2001-11-06-ashcroft.htm

Pellegrino, Edmond D. and David C. Thomasma. *For the Good of the Patient. The Restoration of Beneficence in Health Care.* New York: Oxford University Press. 1988.51-58.

Lynn, Joanne, and Joan Harrold. *Handbook for Mortals: Guidance for People Facing Serious Illness.* New York: Oxford University Press. 1999. 78

Emanuel, Ezekiel, and Linda Emanuel. What is Accountability in Health Care? *Ann Int Med.* 1996; 124: 229-239

Beauchamp, Tom L., and James F. Childress. *Principles of Biomedical Ethics.* 5th Ed. New York: Oxford University Press. 2001.128-132.

Management of Cancer Symptoms: Pain, Depression, and Fatigue. Evidence Report/Technology Assessment: Number 61. *AHRQ Pub. No. 02-E061.* 2002 www.ahrq.gov/clinic/epcsums/csympsum.htm.

Missouri Board of Healing Arts. Model Guidelines for the Use of Controlled Substances for the Treatment of Pain. *Healing Arts News.* 2002 (Spring) 17(1):4-7.

National Pain Education Council Web site: http://www.npecweb.org

PAIN & POLICY STUDIES GROUP

University of Wisconsin Comprehensive Cancer Center
World Health Organization Collaborating Center
for Policy and Communications
Madison, Wisconsin
www.medsch.wisc.edu/painpolicy

Published Resources about Pain Policy for State Medical Boards

Joranson DE, Gilson AM. Controlled substances and pain management: A new focus for state medical boards. *Federation Bulletin: The Journal of Medical Licensure & Discipline*. 1998; 85(2):78-83. www.medsch.wisc.edu/painpolicy/publicat/98fedbul.htm

Gilson AM, Joranson DE. Controlled substances and pain management: Changes in knowledge and attitudes of state medical regulators. *Journal of Pain & Symptom Management*. 2001; 21(3):227-237. www.medsch.wisc.edu/painpolicy/publicat/01jpsm/jpsm01.pdf

Joranson DE, Gilson AM. Pharmacists' knowledge of and attitudes toward opioid pain medications in relation to federal and state policies. *Journal of the American Pharmaceutical Association*. 2001; 41(2):213-220. www.medsch.wisc.edu/painpolicy/publicat/01japhak/01japhak.pdf

Gilson AM, Joranson DE. U.S. policies relevant to the prescribing of opioid analgesics for the treatment of pain in patients with addictive disease. *Clinical Journal of Pain*. 2002; 18(4 suppl):S91-S98. www.medsch.wisc.edu/painpolicy/publicat/02cjpn/Tx_addicts.pdf

Joranson DE, Carrow GM, Ryan KM, Schaefer L, Gilson AM, Good P et al. Pain management and prescription monitoring. *Journal of Pain & Symptom Management*. 2002; 23(3):231-238. www.medsch.wisc.edu/painpolicy/publicat/02jpsm2/pmp.pdf

Joranson DE, Gilson AM, Dahl JL, Haddox JD. Pain management, controlled substances, and state medical board policy: A decade of change. *Journal of Pain & Symptom Management*. 2002; 23(2):138-147. www.medsch.wisc.edu/painpolicy/publicat/02jpsm1/jpsm02.pdf

Joranson DE, Gilson AM, Nischik JA. North Carolina, pain management and end-of-life care: Communicating the policy. *Federation Bulletin: The Journal of Medical Licensure & Discipline*. 2002; 88(3):116-119. www.medsch.wisc.edu/painpolicy/publicat/02fsmb/jmld02.pdf

Gilson AM, Joranson DE, Maurer MA. Improving state medical board policies: Influence of a model. *Journal of Law, Medicine & Ethics*. 2003; 31(1):119-129. www.medsch.wisc.edu/painpolicy/publicat/03jlme/jlme_model.pdf

Pain & Policy Studies Group. *Achieving balance in federal and state pain policy: A guide to evaluation (2nd edition)*. Madison, WI: University of Wisconsin Comprehensive Cancer Center, 2003. www.medsch.wisc.edu/painpolicy/eguide2003/index/eguide2003.pdf

Pain & Policy Studies Group. *Achieving balance in state pain policy: A progress report card*. Madison, WI: University of Wisconsin Comprehensive Cancer Center, 2003. www.medsch.wisc.edu/painpolicy/2003_balance/prc2003.pdf

Gilson AM, Ryan KM, Joranson DE, Dahl JL. A reassessment of trends in the medical use and abuse of opioid analgesics and implications for diversion control: 1997-2002. *Journal of Pain & Symptom Management*. 2004; 28(2):176-188. www.medsch.wisc.edu/painpolicy/publicat/04jpsm/04jpsm.pdf

PAIN & POLICY STUDIES GROUP

University of Wisconsin Comprehensive Cancer Center
World Health Organization Collaborating Center
for Policy and Communications
Madison, Wisconsin
www.medsch.wisc.edu/painpolicy

Resources about Pain Policy for State Pharmacy Boards

Joranson DE, Gilson AM. Pharmacists' knowledge of and attitudes toward opioid pain medications in relation to federal and state policies. *Journal of the American Pharmaceutical Association*. 2001; 41(2):213-220. www.medsch.wisc.edu/painpolicy/publicat/01japhak/01japhak.pdf

Gilson AM, Joranson DE. U.S. policies relevant to the prescribing of opioid analgesics for the treatment of pain in patients with addictive disease. *Clinical Journal of Pain*. 2002; 18(4 suppl):S91-S98. www.medsch.wisc.edu/painpolicy/publicat/02cjpn/Tx_addicts.pdf

Joranson DE, Carrow GM, Ryan KM, Schaefer L, Gilson AM, Good P et al. Pain management and prescription monitoring. *Journal of Pain & Symptom Management*. 2002; 23(3):231-238. www.medsch.wisc.edu/painpolicy/publicat/02jpsm2/pmp.pdf

Pain & Policy Studies Group. *Achieving balance in federal and state pain policy: A guide to evaluation (2nd edition)*. Madison, WI: University of Wisconsin Comprehensive Cancer Center, 2003. www.medsch.wisc.edu/painpolicy/eguide2003/index/eguide2003.pdf

Pain & Policy Studies Group. *Achieving balance in state pain policy: A progress report card*. Madison, WI: University of Wisconsin Comprehensive Cancer Center, 2003. www.medsch.wisc.edu/painpolicy/2003_balance/prc2003.pdf

Gilson AM, Ryan KM, Joranson DE, Dahl JL. A reassessment of trends in the medical use and abuse of opioid analgesics and implications for diversion control: 1997-2002. *Journal of Pain & Symptom Management*. 2004; 28(2):176-188. www.medsch.wisc.edu/painpolicy/publicat/04jpsm/04jpsm.pdf

National Association of Boards of Pharmacy (NABP) endorsement of Federation of State Medical Board's "Model Guidelines for the Use of Controlled Substances for the Treatment of Pain." http://www.medsch.wisc.edu/painpolicy/domestic/nabp01.htm.

Pharmacy Board policy statements:

CA http://www.medsch.wisc.edu/painpolicy/domestic/caphar96.htm
IA http://www.medsch.wisc.edu/painpolicy/domestic/iapharm.htm
TX http://www.medsch.wisc.edu/painpolicy/domestic/txphbd01.htm

Pharmacy board joint policy statements with other boards:

KS http://www.medsch.wisc.edu/painpolicy/domestic/ksjtstmnt02.htm
MNhttp://www.state.mn.us/mn/externalDocs/BMP/BMP_Joint_Policy_Statement_091404112418_Joint%20Statement%20on%20Pain%20Management.htm
NC http://www.medsch.wisc.edu/painpolicy/domestic/ncjoint.htm
WVhttp://www.medsch.wisc.edu/painpolicy/domestic/wvjoint.htm

(NAGPRA), 25 U.S.C. 3005, of the intent to repatriate a cultural item in the possession of the Heard Museum, Phoenix, AZ, that meets the definition of ''cultural patrimony'' under 25 U.S.C. 3001.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003 (d)(3). The determinations in this notice are the sole responsibility of the museum that has control of the cultural item. The National Park Service is not responsible for the determinations in this notice.

The one cultural item is a Dilzini Gaan headdress made of painted wood and cloth.

It is not known exactly when, where, or by whom the headdress was collected, or under what circumstances the Heard Museum acquired the headdress. The museum probably acquired the headdress before 1952, since the museum's collections were re-cataloged after 1951, and the headdress appears to match a catalog description that was probably written between 1931 and 1947.

Representatives of the Mescalero Apache Tribe of the Mescalero Reservation, New Mexico; San Carlos Apache Tribe of the San Carlos Reservation, Arizona; Tonto Apache Tribe of Arizona; White Mountain Apache Tribe of the Fort Apache Reservation, Arizona; and Yavapai-Apache Nation of the Camp Verde Indian Reservation, Arizona examined the museum's collections, consulted with museum staff, and identified the headdress as an object of cultural patrimony eligible for repatriation under NAGPRA. The White Mountain Apache Tribe demonstrated that the cultural item has ongoing traditional and cultural importance to the tribe and could not have been conveyed by any individual tribal member.

Officials of the Heard Museum have determined that, pursuant to 25 U.S.C. 3001 (3)(D), the cultural item has ongoing historical, traditional, or cultural importance central to the White Mountain Apache Tribe of the Fort Apache Reservation, Arizona, rather than property owned by an individual. Officials of the Heard Museum also have determined that, pursuant to 25 U.S.C. 3001 (2), there is a relationship of shared group identity that can be reasonably traced between the object of cultural patrimony and the White Mountain Apache Tribe of the Fort Apache Reservation, Arizona.

Representatives of any other Indian tribe that believes itself to be culturally affiliated with the object of cultural patrimony should contact Frank Goodyear, Director, Heard Museum, 2301 N. Central Avenue, Phoenix, AZ 85004, telephone (602) 252-8840, before December 16, 2004. Repatriation of the object of cultural patrimony to the White Mountain Apache Tribe of the Fort Apache Reservation, Arizona may proceed after that date if no additional claimants come forward.

The Heard Museum is responsible for notifying the Apache Tribe of Oklahoma; Fort Sill Apache Tribe of Oklahoma; Jicarilla Apache Nation, New Mexico; Mescalero Apache Tribe of the Mescalero Reservation, New Mexico; San Carlos Apache Tribe of the San Carlos Reservation, Arizona; Tonto Apache Tribe of Arizona; White Mountain Apache Tribe of the Fort Apache Reservation, Arizona; and the Yavapai-Apache Nation of the Camp Verde Indian Reservation, Arizona that this notice has been published.

Mary Downs,

Acting Manager, National NAGPRA Program

[FR Doc. 04–25353 Filed 11–15–04; 8:45 am]

BILLING CODE 4312–50–S

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–258S]

Dispensing of Controlled Substances for the Treatment of Pain

AGENCY: Drug Enforcement Administration (DEA), Department of Justice.

ACTION: Interim policy statement.

SUMMARY: In August 2004, DEA published on its Office of Diversion Control Web site a document entitled: ''Prescription Pain Medications: Frequently Asked Questions and Answers for Health Care Professionals and Law Enforcement Personnel'' (August 2004 FAQ). The August 2004 FAQ was not published in the **Federal Register** and was not an official statement of the agency. DEA subsequently withdrew the document because it contained misstatements. This interim policy statement explains how some of the statements in the August 2004 FAQ were erroneous. In addition, this interim statement explains how DEA plans to address in a future **Federal Register** document the issue of dispensing controlled substances for the treatment of pain.

FOR FURTHER INFORMATION CONTACT: William J. Walker, Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537; Telephone: (202) 307–7165.

SUPPLEMENTARY INFORMATION: In August 2004, DEA published on its Office of Diversion Control Web site a document entitled: ''Prescription Pain Medications: Frequently Asked Questions and Answers for Health Care Professionals and Law Enforcement Personnel'' (August 2004 FAQ). For the reasons provided below, the August 2004 FAQ was not an official statement of the agency and DEA subsequently withdrew the document because it contained misstatements. Nonetheless, the subject matter—dispensing controlled substances for the treatment of pain—is extremely important to the public health and welfare. As the agency primarily responsible for enforcement and administration of the federal laws and regulations governing controlled substances, DEA believes that further discussion of the subject is warranted for two fundamental reasons. First, the abuse of pharmaceutical narcotics and other prescription controlled substances is increasing in the United States. According to the latest National Survey on Drug Use and Health, which is published by the Department of Health and Human Services, Substance Abuse and Mental Health Services Administration (SAMHSA), the number of Americans aged 12 or older who have engaged in illicit (nonmedical) use of pain relievers during their lifetime has risen to more than 31 million.[1] A portion of this type of drug abuse is directly facilitated by a small number of physicians who dispense controlled substances for other than legitimate medical purposes and then fraudulently claim that the drugs were dispensed for the treatment of pain.

Second, chronic pain is a serious problem for many Americans. It is crucial that physicians who are engaged in legitimate pain treatment not be discouraged from providing proper medication to patients as medically justified. DEA recognizes that the overwhelming majority of physicians dispense controlled substances lawfully for legitimate medical reasons, including the treatment of pain. Accordingly, DEA plans to address the subject of dispensing controlled substances for the treatment of pain in a future **Federal Register** document, taking into consideration the views of the medical community. The document will be aimed at providing guidance and reassurance to physicians who engage in

[1] The report is available on the SAMHSA Web site at *http://oas.samhsa.gov/NHSDA/2k3NSDUH/2k3results.htm.*

legitimate pain treatment while deterring the unlawful conduct of a small number of physicians and other DEA registrants who exploit the term ''pain treatment'' as a pretext to engage in prescription drug trafficking. In the meantime, the agency wishes to correct here a few of the significant misstatements contained in the August 2004 FAQ.

Misstatements in the August 2004 FAQ

Although not an exhaustive discussion, the following is an explanation of some of the misstatements that were contained in the August 2004 FAQ.

Commencement of investigations—The August 2004 FAQ erroneously stated: ''The number of patients in a practice who receive opioids, the number of tablets prescribed for each patient, and the duration of therapy with these drugs do not, by themselves, indicate a problem, and they should not be used as the sole basis for an investigation by regulators or law enforcement.'' In fact, each of the foregoing factors—though not necessarily determinative—may indeed be indicative of diversion. As one federal appeals court has correctly stated, one can glean from the reported cases in which physicians have been convicted of dispensing controlled substances for other than a legitimate medical purpose ''certain recurring concomitance of condemned behavior,'' such as the following:

(1) An inordinately large quantity of controlled substances was prescribed.
(2) Large numbers of prescriptions were issued.
(3) No physical examination was given.
(4) The physician warned the patient to fill prescriptions at different drug stores.
(5) The physician issued prescriptions to a patient known to be delivering the drugs to others.
(6) The physician prescribed controlled drugs at intervals inconsistent with legitimate medical treatment.
(7) The physician involved used street slang rather than medical terminology for the drugs prescribed.
(8) There was no logical relationship between the drugs prescribed and treatment of the condition allegedly existing.
(9) The physician wrote more than one prescription on occasions in order to spread them out.

United States v. *Rosen,* 582 F.2d 1032, 1035–1036 (5th Cir. 1978) (citations omitted).

Moreover, it is a longstanding legal principle that the Government ''can investigate merely on suspicion that the law is being violated, or even just because it wants assurances that it is not.'' *United States* v. *Morton Salt Co.,* 338 U.S. 632, 642–643 (1950). It would be incorrect to suggest that DEA must meet some arbitrary standard or threshold evidentiary requirement to commence an investigation of a possible violation of the Controlled Substances Act (CSA).

Refills of schedule II prescriptions—The August 2004 FAQ stated: ''Schedule II prescriptions may not be refilled; *however, a physician may prepare multiple prescriptions on the same day with instructions to fill on different dates.*'' (Italics added.) The first part of this sentence is correct, as the CSA expressly states: ''No prescription for a controlled substance in schedule II may be refilled.'' 21 U.S.C. 829(a). However, the second part of the sentence (italicized above) is incorrect. For a physician to prepare multiple prescriptions on the same day with instructions to fill on different dates is tantamount to writing a prescription authorizing refills of a schedule II controlled substance. To do so conflicts with one of the fundamental purposes of section 829(a). Indeed, as the factors quoted above from the Rosen case indicate, writing multiple prescriptions on the same day with instructions to fill on different dates is a recurring tactic among physicians who seek to avoid detection when dispensing controlled substances for unlawful (nonmedical) purposes. It is worth noting here that the DEA regulations setting forth the requirements for the issuance of a controlled substance prescription are set forth in 21 CFR 1306.01–1306.27.

Reselling of controlled substances—The August 2004 FAQ listed a number of behaviors, or ''red flags,'' that are ''probable indicators of abuse, addiction, or diversion.'' These behaviors include ''selling medications.'' The document suggested that certain steps be taken to deal with such indicators, including ''appropriate management'' and possible referral to an addiction specialist. The document went on to state that these behaviors (including reselling medications) ''should not be taken to mean that a patient does not have pain, or that opioid therapy is contraindicated.'' The document also stated: ''Management may or may not include continuation of therapy, depending on the circumstances.'' Finally, the document stated that ''if continued opioid therapy makes medical sense, then the therapy may be continued, even if drug abuse has occurred. Additional monitoring and oversight of patients who have experienced such an episode is *recommended.*'' (Italics added.)

The behaviors listed in the August 2004 FAQ as ''red flags'' are indeed indicators of possible diversion. However, the August 2004 FAQ understated the degree of caution that a physician must exercise to minimize the likelihood of diversion when dispensing controlled substances to known or suspected addicts. If a physician is aware that a patient is a drug addict and/or has resold prescription narcotics, it is not merely ''recommended'' that the physician engage in additional monitoring of the patient's use of narcotics. Rather, as a DEA registrant, the physician has a responsibility to exercise a much greater degree of oversight to prevent diversion in the case of a known or suspected addict than in the case of a patient for whom there are no indicators of drug abuse. Under no circumstances may a physician dispense controlled substances with the knowledge that they will be used for a nonmedical purpose or that they will be resold by the patient.

In a similar vein, the August 2004 FAQ incorrectly minimized the potential significance of a family member or friend expressing concern to the physician that the patient may be abusing the pain medication. The document stated:

Family and friends, or health care providers who are not directly involved in the therapy, may express concerns about the use of opioids. These concerns may result from a poor understanding of the role of this therapy in pain management or from an unfounded fear of addiction; they may be exacerbated by widespread, sometimes inaccurate media coverage about abuse of opioid pain medications.

While it is true that concerns of family members are not always determinative of whether the patient is engaged in drug abuse, the above-quoted statement is incorrect to the extent it implies that physicians may simply disregard such concerns expressed to them by family members or friends. Indeed, a family member or friend might be aware of information that the physician does not possess regarding a patient's drug abuse. Given the addictive and sometimes deadly nature of prescription narcotic abuse, the tremendous volume of such drug abuse in the United States, and the propensity of many drug addicts to attempt to deceive physicians in order to obtain controlled substances for the purpose of abuse, a physician should seriously consider any sincerely expressed concerns about drug abuse conveyed by family members and friends.

It bears emphasis that none of the principles summarized above is new. Rather, these are concepts that have been incorporated for more than 80

years into the federal laws and regulations governing drugs of abuse and are reflected in published federal court decisions and DEA final administrative orders. A more detailed recitation of these principles, as they relate to the dispensing of controlled substances for the treatment of pain, will be provided in a future **Federal Register** document to be published by the agency.

Nature of This Document and the August 2004 FAQ Under the Administrative Procedure Act

This document is a statement of policy within the meaning of the Administrative Procedure Act (APA). It is termed an ''interim'' statement to indicate that a more complete statement on the subject will subsequently be issued by the agency. (Given the misstatements in the August 2004 FAQ, and the significant questions DEA has received following the withdrawal of that document, an immediate preliminary explanation is warranted.) The APA expressly requires agencies to make available to the public and publish in the **Federal Register** statements of general policy and interpretations formulated and adopted by the agency. 5 U.S.C. 552(a)(1)(D). Further, the APA contemplates that agencies shall issue policy statements without engaging in the notice-and-comment proceedings that are required for legislative rules. 5 U.S.C. 553(b)(A). This is because policy statements, unlike legislative rules, are not binding. Consistent with these APA principles, this document does *not* create any new substantive requirements or change the rights and duties of any member of the public; nor is DEA applying the CSA or DEA regulations in a new manner as a result of this document. Rather, this document provides the public with DEA's policy for ensuring that the law administered by the agency relating to the subject matter of this document is faithfully executed.

It also bears emphasis that the August 2004 FAQ was *not* an official statement of the agency. As indicated above, the APA requires publication in the **Federal Register** of agency policy statements or interpretations of the law administered by the agency. The August 2004 FAQ was not published by the agency in the **Federal Register** and did not constitute an authoritative or official statement of the agency.

Dated: November 12, 2004.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. 04–25469 Filed 11–12–04; 10:57 am]

BILLING CODE 4410–09–U

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–249F]

Controlled Substances: Final Revised Aggregate Production Quotas for 2004

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Notice of final aggregate production quotas for 2004.

SUMMARY: This notice establishes final 2004 aggregate production quotas for controlled substances in Schedules I and II of the Controlled Substances Act (CSA). The DEA has taken into consideration comments received in response to a notice of the proposed revised aggregate production quotas for 2004 published September 9, 2004 (69 FR 54703).

EFFECTIVE DATE: November 16, 2004.

FOR FURTHER INFORMATION CONTACT: Christine A. Sannerud, Ph.D., Chief, Drug and Chemical Evaluation Section, Drug Enforcement Administration, Washington, DC 20537, Telephone: (202) 307–7183.

SUPPLEMENTARY INFORMATION: Section 306 of the CSA (21 U.S.C. 826) requires that the Attorney General establish aggregate production quotas for each basic class of controlled substance listed in Schedules I and II. This responsibility has been delegated to the Administrator of the DEA by Section 0.100 of Title 28 of the Code of Federal Regulations. The Administrator, in turn, has redelegated this function to the Deputy Administrator, pursuant to Section 0.104 of Title 28 of the Code of Federal Regulations.

The 2004 aggregate production quotas represent those quantities of controlled substances in Schedules I and II that may be produced in the United States in 2004 to provide adequate supplies of each substance for: the estimated medical, scientific, research and industrial needs of the United States; lawful export requirements; and the establishment and maintenance of reserve stocks (21 U.S.C. 826(a) and 21 CFR 1303.11). These quotas do not include imports of controlled substances.

On September 9, 2004 a notice of the proposed revised 2004 aggregate production quotas for certain controlled substances in Schedules I and II was published in the **Federal Register** (69 FR 54703). All interested persons were invited to comment on or object to these proposed aggregate production quotas on or before September 30, 2004.

Eight companies commented on a total of 15 Schedules I and II controlled substances within the published comment period. The companies commented that the proposed aggregate production quotas for amphetamine, codeine (for conversion), fentanyl, hydrocodone, hydromorphone, marihuana, methamphetamine (for conversion), methamphetamine (for sale), methylphenidate, morphine (for conversion), morphine (for sale), opium, tetrahydrocannabinols, and thebaine were insufficient to provide for the estimated medical, scientific, research, and industrial needs of the United States, for export requirements and for the establishment and maintenance of reserve stocks.

DEA has taken into consideration the above comments along with the relevant 2003 year-end inventories, initial 2004 manufacturing quotas, 2004 export requirements, actual and projected 2004 sales and use, and research and product development requirements. Based on this information, the DEA has adjusted the final 2004 aggregate production quotas for codeine (for conversion), fentanyl, hydromorphone, methamphetamine (for conversion), methamphetamine (for sale), methylphenidate, morphine (for sale), tetrahydrocannabinols, and thebaine to meet the legitimate needs of the United States.

Regarding amphetamine, hydrocodone, marihuana, morphine (for conversion), and opium the DEA has determined that the proposed revised 2004 aggregate production quotas are sufficient to meet the current 2004 estimated medical, scientific, research, and industrial needs of the United States and to provide for adequate inventories.

Therefore, under the authority vested in the Attorney General by Section 306 of the Controlled Substances Act of 1970 (21 U.S.C. 826), and delegated to the Administrator of the DEA by Section 0.100 of Title 28 of the Code of Federal Regulations, and redelegated to the Deputy Administrator, pursuant to Section 0.104 of Title 28 of the Code of Federal Regulations, the Deputy Administrator hereby orders that the 2004 final aggregate production quotas for the following controlled substances, expressed in grams of anhydrous acid or base, be established as follows:

[Federal Register: January 18, 2005 (Volume 70, Number 11)][Notices]
[Page 2883]
From the Federal Register Online via GPO Access [wais.access.gpo.gov]
[DOCID:fr18ja05-75]

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-261N]

Solicitation of Comments on Dispensing of Controlled Substances for the Treatment of Pain

AGENCY: **Drug Enforcement Administration** (DEA), Department of Justice.

ACTION: Notice; solicitation of comments.

SUMMARY: On November 16, 2004, DEA published in the Federal Register an Interim Policy Statement on the dispensing of controlled substances for the treatment of pain. The Interim Policy Statement stated that DEA would address the subject in greater detail in a future Federal Register document, taking into consideration the views of the medical community. DEA is hereby seeking comments from physicians and other interested members of the public as to what areas of the law relating to the dispensing of controlled substances for the treatment of pain they would like DEA to address in the upcoming Federal Register document.

DATES: Written comments must be postmarked, and electronic comments must be sent, on or before March 21, 2005.

ADDRESSES: To ensure proper handling of comments, please reference ``Docket No. DEA-261'' on all written and electronic correspondence. Written comments being sent via regular mail should be sent to the Deputy Administrator, **Drug Enforcement Administration**, Washington, DC 20537, Attention: DEA Federal Register Representative/CCD. Written comments sent via express mail should be sent to DEA Headquarters, Attention: DEA Federal Register Representative/CCD, 2401 Jefferson-Davis Highway, Alexandria, VA 22301. Comments may be directly sent to DEA electronically by sending an electronic message to dea.diversion.policy@usdoj.gov. Comments may also be sent electronically through http://www.regulations.gov using the electronic comment form provided on that site. An electronic copy of this document is also available at the http://www.regulations.gov Web site. DEA will accept attachments to electronic comments in Microsoft Word, WordPerfect, Adobe PDF, or Excel file formats only. DEA will not accept any file format other than those specifically listed here.

FOR FURTHER INFORMATION CONTACT: Daniel Dormont, Senior Attorney, **Drug Enforcement Administration**, Washington, DC 20537; telephone: (202) 307-8010.

SUPPLEMENTARY INFORMATION:

On November 16, 2004, DEA published in the Federal Register an Interim Policy Statement on the dispensing of controlled substances for the treatment of pain. 69 FR 67170. The Interim Policy Statement explained why an earlier document, which appeared on the DEA Office of Diversion Control Web site in August 2004, contained misstatements and was not approved as an official statement of the agency. The Interim Policy Statement corrected some of the misstatements in the August 2004 document and announced that DEA would address, in greater

detail, the subject of dispensing controlled substances for the treatment of pain in a future Federal Register document, taking into consideration the views of the medical community. This upcoming document will stay within the scope of DEA's authority by addressing the law the agency administers, the Controlled Substances Act (CSA), and the DEA regulations promulgated thereunder, as well as the pertinent court decisions. As indicated in the Interim Policy Statement, the document will contain a recitation of the relevant provisions of the CSA and DEA regulations relating to the dispensing of controlled substances for the treatment of pain. The purpose of this recitation will be to provide guidance and reassurance to the overwhelming majority of physicians who engage in legitimate pain treatment while deterring unlawful prescribing and dispensing of pharmaceutical controlled substances. As was the case with the Interim Policy Statement, none of the principles addressed in the upcoming Federal Register document will be new. Rather, the document will reiterate legal concepts that have been incorporated in the federal laws and regulations for many years and are reflected in federal court decisions and DEA final administrative orders. DEA recognizes the desire of many physicians and members of the public to have these concepts reiterated in a single, comprehensive document. Toward that end, DEA is hereby seeking the input of physicians, pharmacists, and other interested members of the public. Any person who so desires should indicate, in writing, the areas of the law relating to controlled substances that they would like DEA to address in the upcoming document. DEA will consider all such comments submitted on or before March 21, 2005.

Dated: January 11, 2005.
Michele M. Leonhart,
Deputy Administrator.
[FR Doc. 05-906 Filed 1-14-05; 8:45 am]
BILLING CODE 4410-09-P

Distinguishing Between Criminal vs. Incompetent/Negligent and Acceptable Practice

Presented by:

June L. Dahl, PhD
Professor, Pharmacology
University of Wisconsin Medical School
Director, Wisconsin Cancer Pain Institute

Bill Marcus, JD
Consultant

Ed Covington, MD
Head, Section on Pain Management, Dept. of Psychiatry
Cleveland Clinic Foundation

Pain Management: What Factors Might Make Prescribing Actionable

FSMB/NABP Workshop
Bill Marcus, J.D.
April 7-8, 2005
Boston, Massachusetts

Remember the Basic Law of Controlled Substances:

It is illegal to distribute controlled substances

21 United States Code §841

For Good or For Ill:

- All authority to manufacture, order, prescribe, administer, or dispense controlled substances is an exception to the basic rule

WHAT CONSTITUTES A LEGAL PRESCRIPTION

- *"A prescription for a controlled substance, to be effective, must be issued for a legitimate medical purpose …in the usual course of…professional practice.*

  "The responsibility for the proper prescribing and dispensing...is upon the [prescriber], but a corresponding responsibility rests with the pharmacist who fills the prescription."

"An order issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of [the Act] and the person knowingly filling [it], as well as the person issuing it, shall be subject to the penalties provided for violation of the [Act]."

21 CFR 1306.04(a)

Sources for Standards for Propriety of Practitioner Conduct

- A. Community practice/experience/education
- B. Literature
- C. Statutes and regulations
- D. Published federal and state court decisions
- E. *Association statements and/or guidelines (e.g., AMA, APS/AAPM)
- F. *JCAHO standards
- G. *Government practice guidelines
- H. *Model guidelines (e.g., the FSMB policy)

* Policies/guidelines/standards are influential, even if not binding

FSMB Policy—a few key elements

- Diagnosis and treatment of pain essential to practice of medicine
- Controlled substances, inc. opioids, can be essential to treatment of pain, including chronic pain
- Diversion and abuse exist, so physicians should incorporate safeguards into their practices
- Exercise sound clinical judgment, clearly document pain, have a real physician-patient relationship

Policies and Guidelines, Generally

- Generally unenforceable by agency unless in statute or regulation
- Serve to tell practitioners how the agency interprets statutes/regulations/standards of practice
- May protect practitioner who follows them in good faith and relatively competently
- But may not protect in criminal prosecutions by other agencies/jurisdictions

In Evaluating Prescribing Practices, Consider:

- The practice environment
- The practitioner's behavior/practices
- The information available to the practitioner
  - From the patient/patient's representatives
  - From examination/tests/prior records
  - From other, credible and relevant sources
- Factors about the drugs
- Factors about the patient (appearance/conduct/history/honesty)
- And see handout of cases/factors/laws

So When Is Prescribing Actionable?

- *Can* file vs. *should* file?
- Who decides?
- The role of proper medical expertise
  - Qualifications of expert
  - Use of expert
  - Credibility of opinion(s)
- Judgment (good or poor) vs. failure to exercise judgment (corrupt or verging on corrupt?)

The Boundaries Between Discipline and Criminal Action

- "Simple" carelessness/negligence/malpractice
- "Extreme" recklessness (such as disregard for possible consequences)
- Knowing violation of a law, including "deliberately ignoring or studiously avoiding" known facts (U.S. v. Kershman, 555 F. 2d. 178 (8th.cir, 1977))—i.e., hiding one's head in the sand
- Intentional violation of a law

The role of "good faith"

- What is "good faith"
- How does it relate to charges of malpractice/gross negligence/practice below the standard of care
- When can it or should it be relevant to a charge of criminal issuance of prescriptions?
  - State vs. Naramore (Kansas—see handout): good faith as defense to charge of illegitimate prescribing

Evidence

- When can one charge "criminal" prescribing in the absence of direct testimony (observed conduct, including undercover operations) or admissions?
  - A volume of prescriptions?
  - Analysis of records?
  - A consideration of documentary, physical and testimonial evidence?
- The role of expert testimony

Basic Types of Criminal Charges

- Prescription violations:
  - Knowing issuance of prescriptions for controlled substances other than in the usual course of professional practice and for one not under one's treatment for a condition other than addiction (see 21 CFR 1306.04(a), discussed above)
- Illegal sale/trafficking (United States v. Moore, 423 U.S. 122 (1975)
- Fraud (documents, insurance, Medicare/medicaid)

Charges When a Patient Dies

- Homicide
  - Manslaughter
    - Involuntary (driving deaths as prime example)
    - Voluntary (careless, with higher risk of death)
  - Murder
    - 2nd degree (People v. Protopappas)
    - 1st degree (generally, premeditated killing with "malice aforethought")
    - Felony/murder rule (People v. Graves)

Cause and Effect

- When is a death "just" a death? (cause and effect)
- Did the drugs prescribed in fact cause death?
- Did the doctor intend they would? Know they would?
- Was his/her conduct outrageous (with a high probability or risk of death)?
- Or careless?
- *Or entirely appropriate* ?

Some Special Concerns About Patients with Drug Problems

- Prescribing/dispensing to addicts only as auth'd by law --restrictions on where, which drugs, amounts

  --but see 2000 federal auth. for office-based tx as superceding state limits; auth. for buprenorphine in NTPs; auth. for two trade versions of buprenorphine in office-based tx)
- Legality of prescribing CS to addict/abuser for treatment of condition other than addiction (such as pain); see MBC guidelines, inc. revisions
- Abuse (such as doctor-shopping) vs. Opiophobia and pseudoaddiction (the result of undertreatment)

- Continuing to treat a patient with compliance problems isn't inherently misconduct
- The key: taking control and setting limits
- Not simply abandoning, but…
  - Not ignoring obvious warning signs
  - Not continuing treatment unabated despite refusal of patient to come into compliance
  - Not countenancing evidence of diversion

Some examples of standard setting/defining cases: Failure to provide sufficient relief

- I. Bergman v. Chin, California (liability for elder abuse through under use of opioids)
- II. Bilder, Oregon (discipline for failure to adequate treat geriatric patients with opioids); similar CA cases

Seminal cases charging improvident use of opioids

- I. (many fed and state cases, especially in 70s and 80s, after CS acts enacted, see handout): disc. for large volume, *unjustified* (inc. lack of documentation) patterns of prescribing
- II. Fisher, California; Weitzel, Utah (homicide prosecution in connection with prescribing opioids: note ultimate acquittal in these two cases)
- III. Graves, Florida (felony-murder conviction, illegal felony prescriptions with patients who died)

- IV. Hurwitz, Virginia (earlier discipline, charged with racketeering, being a "drug kingpin", ultimately 50 count conviction in late 2004, although not for being a drug kingpin, facing many years in prison)
- V. Naramore, Kansas (credible evidence of good faith as defense to prosecution for attempted murder/murder, conviction overturned)
- VI. Apparent confusion of cause and effect (filing because of death without clear evidence of legal causation)

Thank You!

Bill Marcus, J.D.
(BILLNOPAIN@aol.com)
FSMB Workshop, March 2, 2005

Notes:

To Think About:

1. What triggered the investigation?
2. What information would be needed/appropriate to determine if there are violations?
3. Who should be determining whether to file or what to file, including:
    a. What the information means
    b. Whether there are violations
    c. Whether to file charges
    d. What charges to file
4. What is the role of the expert? Who should the expert be?
5. If charges are to be filed, what level (informal, disciplinary, criminal)?
6. What would justify criminal charges?
    a. Ordinary negligence/carelessness/malpractice?
    b. Recklessness?
    c. Issuing prescriptions knowing they are questionable/probable patient use of them is questionable?
    d. Issuing prescriptions knowing/intending the drugs will be misused/diverted?
7. What establishes criminal behavior according to the above?
    a. Only direct admissions by the physician?
    b. Direct evidence demonstrating knowledge and intent

c. Evidence of overall conduct demonstrating lack of good faith medical practice (that is, no reasonable practitioner would have issued the prescriptions under the same circumstances)

d. The fact of serious patient injuries or death(s)?

8. What does the fact a patient has (or patients have) died establish?

a. Elderly or fragile patients? Terminally ill/hospice/palliative care patients?

b. Active drug abusers in pain?

BASIC CASE LAW (an overview)
(FSMB/NABP Workshops, 2005)

1. Basic Legal Standards

A. Practitioner may prescribe or dispense only within the course of professional practice (21 U.S.C.§802(20); the practitioner who knowingly steps outside the bounds of professional practice is subject to prosecution for illegal distribution of drugs, not just the lesser crime of issuing or dispensing an illegitimate prescription (United States v. Moore (1975) 423 U.S. 122, People v. Gandotra (1992) 11 Cal.App.4th 1355, Perzik v. Superior Court (1991) 2 Cal.App.4th 898, and People v. Alford (1979, Mich) 251 N.W.2d 314 and State v. Carr (1981, N.M.) 626 P.2d 292; see also Merriman v. State (1980, Texas) 594 S.W.2d 410, holding the same for pharmacists).

A pharmacist may be prosecuted for illegal possession for sale (a felony/misdemeanor), not just violations of the Pharmacy Law or of the prescription sections of the U.C.S.A., even though the drugs were obtained through a pharmacy license and although the conduct occurred in the pharmacy (People v. Doss (1992) 4 C.A.4th 1585, citing U.S. v. Moore, cited above). A physician may be prosecuted for illegal sale of controlled substances based on issuing illegitimate prescriptions, not just for issuing an invalid prescription, if the prescription was not issued in good faith (Perzik v. Superior Court and People v. Gandotra, cited above

B. It is not enough that a prescription is technically correct in form (Jin Fuey Moy v. United States (1920) 254 U.S. 189; People v. Cliche (1982, Ill.) 444 N.E.2d 649; Com. v. West (1979, Pa.) 411 A.2d 537; State v. Carr, supra)

C. A physician whose conduct amounts to diversion is a pusher (United States v. Badia (1973, 1st Cir.) 490 F.2d 296; United States v. Moore, supra. The same is true for a pharmacist (United States v. Henry (1984, 5th Cir.) 727 F.2d 1373)

D. There must be a legitimate medical purpose and an actual physician-patient relationship (see White v. United States (1968, 8th. cir.) 399 F.2d 813; Dunford v. United States (1954, 4th. cir.) 216 F.2d 184)

E. There must be more than a sham examination and indication (United States v. Perry-Hooker (1976, 1st cir.) 541 F.2d 300; A, B, C, and D are often phrased as requiring, at least for criminal prosecution, a lack of "good faith" on the practitioner's part (see United States v. Pay Ming Leu (1975, 7th cir) 511 F.2d 1062 and People v. Kwoh Cheng Sun (1980, Mich) 290 N.W.2d 68), honesty of purpose, lack of intent to defraud and being faithful to one's duty or obligation (People v. Lonergan (1990) 219 Cal. App.3d 82) or an "honest effort" (People v. Alford, supra)

F. "Good faith" as defense to criminal charges (homicide/attempted murder) where conflicting, mutually credible evidence as to whether conduct was, or was not, in good faith (State v. Naramore (1998, Kansas, App.Ct.) 965 P.2d 211)

G. The crime is complete upon issuance of the prescription and delivery to the "patient" (United States v. Davis (1977, 9th cir.) 564 F.2d 840), regardless of whether the prescription is filled (United States v. Flowers (1987, 6th Cir.) 818 F.2d 464)

H. Undercover operations are appropriate to determine illicit activities (United States v. Jobe (1973, 10th cir.) 487 F.2d 268 and White v. State (1978, Ga.) 247 S.E.2d 536)

I. Entrapment requires inducement, not mere solicitation (State v. Moody (1981, La) 393 So.2d 1212 and Arthurs v. Bd. of Registration in Medicine (1981, Mass.) 418 N.E.2d 1236)

J. The knowledge required for a criminal conviction is knowledge of the act committed, not knowledge the act violates the law (People v. Lonergan, supra)

K. A pharmacist may not fill prescriptions where he or she knows they are not for a legitimate medical purpose, and knowledge includes studiously avoiding or deliberately ignoring known facts (U.S. v. Kershman (1977, 8th cir) 555 F.2d 198); a pharmacist must use common sense and professional judgment in filling prescriptions (Vermont & 110th Medical Arts Pharmacy v. Board of Pharmacy of the State of California (1981) 125 C.A.3rd 19), and a pharmacist may be convicted of dealing when he or she dispenses without prescription and not in accordance with his or her registration (Tobias v. State (1985, Indiana) 479 N.E.2d 508) A pharmacist can know prescriptions are not for a legitimate medical purpose without practicing medicine (United States v. Hayes (1979, 5th Cir.) 595 F.2d 258)

L. A pharmacist may be prosecuted for illegal possession for sale (a felony/misdemeanor), not just violations of the Pharmacy Law or of the prescription sections of the U.C.S.A., even though the drugs were obtained through a pharmacy license and although the conduct occurred in the pharmacy (People v. Doss (1992) 4 C.A.4th 1585, citing U.S. v. Moore, cited above)

M. A physician may be prosecuted for illegal sale of controlled substances based on issuing illegitimate prescriptions, not just for issuing an invalid prescription, if the prescription was not issued in good faith (Perzik v. Superior Court (1991) 2 C.A.4th 898

2. Factors which courts have used to find misconduct/diversion:

A. Inordinate quantity of controlled substances dispensed (United States v. Rosen (1978, 5th cir) 582 F.2d 1032

B. Large numbers of prescriptions issued (Rosen)

C. Lack of physical examination and/or history (Rosen; United States v. Varma (1982, 10th Cir.) 691 F.2d 460

D. Prescriber warns patient to fill prescription at different pharmacies (Rosen; United States v. Barbee 1973, 10th Cir.) 497 F.2d 484)

E. Prescriber issued prescriptions to a patient known to be delivering drugs to others (Rosen)

F. Prescriptions issued at intervals inconsistent with legitimate treatment (Rosen; United States v. Stump (1984, 7th Cir.) 735 F.2d 273)

G. Prescriber used street terms to describe drugs (Rosen)

H. Lack of any logical relationship between the drugs prescribed and treatment of the condition allegedly existing (Rosen)

I. Patient's condition does not improve (or worsens) (Padilla v. Mn. State Bd. of Medicine (1986, Minn.) 382 N.W.2d 876)

J. Prescriber wrote more than one prescription on one occasion in order to spread them out (Rosen)

K. Willingness of prescriber to engage in future drug deals, including street drugs (United States v. Dunbar (1980, 5th cir) 614 F.2d 39, cert.den. 447 U.S. 926 (1980))

L. Charge to patient based on type or number of prescriptions written or quantity prescribed (United States v. Larson (1974, 9th cir) 507 F.2d 385; United States v. Moore, supra; Davis v. State Bd. of Medical Examiners (1951) 108 Cal.App.2d 346)

M. Prescriber wrote prescriptions in other names, often fictitious, given by the patient (People v. Alford, supra; United States v. Stump, supra)

N. Prescriber allowed one patient to get repeat prescriptions for another patient, without the other patient coming in (Com. v. Possinger (1979, Pa.) 399 A.2d 1077)

O. Prescriber asked the patient what patient wanted and gave patient what patient asked for (State v. Kane (1979, Mo.) 586 S.W.2d 812; People v. Demery (1980) 104 Cal.App.3d 551) or the amount the patient wanted (United States v. Moore, supra)

P. Patient used slang terms for the drugs (United States v. Bartee, supra)

Q. Prescriber directed the patient to a particular pharmacy (United States v. Stump, supra)

R. Prescriber showed knowledge of common abuse of the drug (People v. Cliche, supra)

S. Prescriber showed knowledge specific patient abused/misused drug (United States v. Smurthwaite (1979, 10th Cir.) 590 F.2d 889)

T. Patients were not required to make appointments, but just showed up (United States v. Boettjer (1978, 9th cir) 569 F.2d 1078, cert. den. 435 U.S. 976 (1978)

U. Prescriber spent very little time (typically less than 5 minutes) with the patient (United States v. Boettjer, supra; United States v. Ellzey (1976, 6th Cir.) 527 F.2d 1306)

V. Prescriber lacked accurate records (United States v. Moore, supra)

W. Prescriptions were invariably for the same amount (United States v. Jackson (1978, 5th cir) 576 F.2d 46)

X. Patients invariably got the same treatment (United States v. Zwick (1976, Ohio D.C.) 413 F.S. 113; weight pills)

Y. Long lines or crowds at the prescriber's office (People v. Demery, supra)

Z. Use contrary to manufacturer's inserts on drug use (State v. Lawrence (1974, S.C.) 212 S.E.2d 52)

AA. Evidence of street prices (to show motive) (State v. Lawrence, supra)

AB. Evidence of other prescriptions (not charged) to show intent, knowledge, motive, wilfulness, plan and scheme (United States v. Jackson, supra; United States v. Stump, supra)

AC. Price being charged (Matter of Heller (1977, N.J.) 374 A.2d 1191, where a pharmacist marked the price up 400% over his cost)

AD. Physician writes prescriptions for extra money or for services or property (United States v. Stump, supra)

AE. Prescriptions "urgently" needed, but patient in no hurry to fill (United States v. Lawson (1982, 4th cir) 682 F.2d 480)

AF. One person presents a pharmacy with multiple prescriptions in false names (United States v. Hayes, supra; Jacobs v. New York State Educ. Dept. (1984) 477 NYS2d 895)

AG. Patients coming a great distance (United States v. Lawson, supra, where a pharmacist had many Philadelphia residents coming to his D.C. pharmacy, and he failed to investigate why)

AH. Antedating or postdating prescriptions (United States v. Bartee, supra)

AI. Prescriptions filled from one physician in consecutive batches (Vermont & 110th Medical Arts Pharmacy, supra)

AJ. Prescriptions filled in questionable names and/or for non-existent addresses (Vermont & 110th Medical Arts Pharmacy, supra)

AK. Drug orders and/or volume of prescriptions are substantially higher than other, similar practitioners (United States v. Seelig (1980, 6th Cir.) 622 F.2d 207; United States v. Friedman (1919, 6th Cir.) 260 F. 388, where a pharmacy purchased 20 times the amount of morphine purchased by any other area pharmacy and 60 times the average amount)

AL. Practitioner prescribes outside scope of his or her license or specialty, training, or expertise

AM. CF: People v. Chua (1987, Ill.) 509 N.E.2d 533, where conviction was reversed where the physician refused agent request for other controlled substances (besides Valium), refused cash, refused to prescribe for agent's "wife" (who was not present), refused to prescribe narcotic cough syrup, refused to recommend a specific pharmacy, was paid by the visit (not by the prescription), authorized no refills, issued the Valium prescriptions in its weaker strengths, had records which supported his diagnoses and treatment and where the agents' visits were months apart.

III. **Some Key Statutes/Regulations/Policies**

A. Prescribing or dispensing to one not under treatment for a pathology or condition other than addiction to a controlled substance/must be for a legitimate medical purpose in the usual course of professional practice

B. Requirement of medical indication and good faith prior examination

C. Intractable Pain Treatment Act/regulation/policy

D. Pain patient rights

E. Clearly excessive dispensing and furnishing

F. Recordkeeping requirements for all persons and entities who handle prescription controlled substances (or other prescription drugs)

G. Furnishing, etc. to addict (for other than treatment of a condition other than addiction/for treatment or maintenance of addiction, except as authorized by law)

H. Possession, possesion for sale, and sale and trafficking of controlled substances

I. 21 U.S.C. section 841: illegal distribution of controlled substances/trafficking

J. Fraud statutes

K. Homicide statutes (manslaughter, murder, felony/murder)

Federation of State Medical Boards

Promoting Balance and Consistency in the Regulatory Oversight of Pain Care

Table of Contents

What Are We Looking For?

~

Working with Your Legal Team and Expert Witness

Presented by:

Arthur K. Thexton, JD
Prosecuting Attorney
Wisconsin Department of Regulation & Licensing

Scott Fishman, MD
Chief, Division of Pain Medicine
University of California, Davis

What/Who Are We Looking For?

- How can we tell the good from the bad and the ugly?
- What are our criteria, as non-physicians, for our investigative decisions?
- How can we avoid being part of the problem of undertreating pain?

20 Boards (in 15 States) have statutory provisions regarding pain management. (CA, FL, OH)

9 Boards (in 8 additional states) have formal rules (but no statute) regarding pain management. (WA, IA)

21 Boards (in 19 additional states) have guidelines or policies regarding pain management (but no formal rules or statutes). (NY, IL, MA, PA)

Only 10 Boards have no statute, rule, or guideline/policy (leaving 8 states "uncovered"). (CT)

2 states (NJ, MN) plus two boards from two other small states, did not respond. 2 states have a statute or rule for their medical boards, but nothing for their osteopathic boards (WA, WV).

Source: 2003 FSMB Exchange, table 26

A JOINT STATEMENT FROM 21 HEALTH ORGANIZATIONS AND THE DRUG ENFORCEMENT ADMINISTRATION

Promoting Pain Relief and Preventing Abuse of Pain Medications: A Critical Balancing Act

As representatives of the health care community and law enforcement, we are working together to prevent abuse of prescription pain medications while ensuring that they remain available for patients in need.

Both healthcare professionals, and law enforcement and regulatory personnel, share a responsibility for ensuring that prescription pain medications are available to the patients who need them and for preventing these drugs from becoming a source of harm or abuse. We all must ensure that accurate information about both the legitimate use and the abuse of prescription pain medications is made available. The roles of both health professionals and law enforcement personnel in maintaining this essential balance between patient care and diversion prevention are critical.

Preventing drug abuse is an important societal goal, but there is consensus, by law enforcement agencies, health care practitioners, and patient advocates alike, that it should not hinder patients' ability to receive the care they need and deserve.

This consensus statement is necessary based on the following facts:

- Under-treatment of pain is a serious problem in the United States, including pain among patients with chronic conditions and those who are critically ill or near death.
- Effective pain management is an integral and important aspect of quality medical care, and pain should be treated aggressively.
- For many patients, opioid analgesics – when used as recommended by established pain management guidelines – are the most effective way to treat their pain, and often the only treatment option that provides significant relief.
- Because opioids are one of several types of controlled substances that have potential for abuse, they are carefully regulated by the Drug Enforcement Administration and other state agencies. For example, a physician must be licensed by State medical authorities and registered with the DEA before prescribing a controlled substance.
- In spite of regulatory controls, drug abusers obtain these and other prescription medications by diverting them from legitimate channels in several ways, including fraud, theft, forged prescriptions, and via unscrupulous health professionals.
- Drug abuse is a serious problem. Those who legally manufacture, distribute, prescribe and dispense controlled substances must be mindful of and have respect for their inherent abuse potential. Focusing only on the abuse potential of a drug, however, could erroneously lead to the conclusion that these medications should be avoided when medically indicated – generating a sense of fear rather than respect for their legitimate properties.
- Helping doctors, nurses, pharmacists, other healthcare professionals, law enforcement personnel and the general public become more aware of both the use and abuse of pain medications will enable all of us to make proper and wise decisions regarding the treatment of pain.

October 23, 2001

American Academy of Family Physicians
American Academy of Hospice and Palliative Medicine
American Academy of Pain Medicine
American Alliance of Cancer Pain Initiatives
American Cancer Society
American Medical Association
American Pain Foundation
American Pain Society
American Pharmaceutical Association
American Society of Anesthesiologists
American Society of Law, Medicine & Ethics
American Society of Pain Management Nurses
American Society of Regional Anesthesia and Pain Medicine
Community-State Partnerships to Improve End-of-Life Care
Drug Enforcement Administration
Last Acts
Midwest Bioethics Center
National Academy of Elder Law Attorneys
National Hospice and Palliative Care Organization
Oncology Nursing Society
Partnership for Caring, Inc.
University of Wisconsin Pain & Policy Studies Group

Case History

- 36 y.o. married mother struck on head at meat packing plant by meat hook, wearing head protection.
- Titrated up to 16,000 mg MSO_4 qd.
- Consultations by physical medicine.
- Written medication agreement.
- Pharmacist in-person q 2 wks, physician q 4 wks.
- Increasing function and pain control documented and verified with family.
- Titrated down to lower levels (11-12g).

Case History, con't

- **Complaint (by worker's compensation insurance company) closed** No Violation **by MEB, PEB.**
- **MORAL: It's *never* just about quantity.**

The New York Times
October 19, 2004
Doctors Behind Bars: Treating Pain Is Now Risky Business
By SALLY SATEL, M.D.

Consider the clinical experience of a colleague, a neurologist who ran a pain service at a university medical center. He treated a young woman who developed a number of painful disorders including complex regional pain syndrome, psoriatic arthritis and diabetic neuropathy. She was in so much agony that she could get around only in a motorized wheelchair and could barely move her arms to feed herself.

Disuse led to the stiffening of her arm muscles, and surgery was needed to release the tendons. Still, the pain was so excruciating that her doctor had to increase her dose to a staggering 3 grams of oxycodone per day, 90 grams per month - easily 30 to 60 times the standard dose for a person with, say, a painful degenerative disk disease. At this level of pain medication, she was able to get out of bed and use her wheelchair.

- Date: Wed, 24 Nov 2004
- Many years ago, I treated an elderly, cachectic lady who was dying with metastatic laryngeal cancer. When I was initially consulted, she was in agony and her family was very distressed. Over a period of about 2 weeks, I titrated her to about 15 grams per day of I.V. morphine by continuous infusion. At this point she was barely arousable but was comfortable. After several weeks of this, I started weaning her slowly. She became more responsive and remained comfortable. After about a week into the wean with a dose of about half the maximum, she expired quietly one night. She had been expected to live another week or two when I first saw her; but with pain control she lived for another six weeks.
- I have "sedated" many patients on the operating table (mostly for invasive pain management procedures) who were on reasonably modest doses of chronic oral opioids but who required huge doses of intravenous fentanyl, morphine, etc to make them comfortable for rather minor procedures (e.g. caudal epidural steroid injections). In at least some patients, reasonably modest doses of oral opioids seem to induce profound tolerance to higher doses.
- Tom Stinson, MD, Medford, MA

- Dr. William Vilensky DO, R.Ph., at the Wisconsin Osteopathic Association annual conference in October, 2004, said that he reviewed a case of a patient on 3,000mg of morphine per day, and that the patient was functioning as a 7-figure/yr Wall Street tycoon of some kind. Dr. Vilensky viewed the dosage as justified by the unusual circumstances of that case. Dr. Vilensky also stated that he has seen a number of cases of patients appropriately taking 300mg methadone per day.

- Date: Fri, 26 Nov 2004
- From: Joel Hochman MD
- My average intractable pain patient requires from 360 to 480 mg of OxyContin a day to maintain a 4-5 pain level and perform at a reasonable level at their activities of daily living. I have a patient who functions normally on 400 mg of methadone three times a day. (We're going to try an implanted pain pump on him in January.)

From: NADDI Rxnews [mailto:rxn@naddi.org]
Sent: Friday, December 24, 2004 7:52 AM

The day I started my fellowship I was asked by the nursing staff to sign the prescriptions for a patient who was on several HUNDRED 8mg Dilaudid® tablets a day! I refused and, on the first day of my pain fellowship, was dinged by my attending for not doing so.

He explained the natural course of this patient's problems starting with a horrible multiple trauma and spinal cord injury. To document that he actually took this much he was admitted to ICU and watched all day while he did so. He did indeed and was watching a football game eating KFC (illegally brought in) when the attending checked on him after only a couple hundred pills that day. He was very functional on that dose. Shortly thereafter we implanted a drug administration system and he is now walking on his own with crutches off all oral opioid medications.

QUESTION: WHY was the patient taking 1,600 pills a day is my second question. (The first was "is that the right amount"?) Deafferentation syndrome of sorts??? Failed spinal cord stimulation and intrathecal drug administration system? That which appears unbelievable may actually have a reasonable explanation. Remember, there are over 200 million people and all of them get sick and die at some point. Somebody has to be the unlucky SOB that has the worst pain of all these 200 million people. I can tell you the guy I cited, on over 250 Dilaudid® tabs a day, was legit.

Brian F. Griffin, MD, FACEP, DAAPM, DABAPM
Interventional Pain Management
Board Certified, Anesthesia/Pain Subspecialty
Board Certified, Pain Management
Board Certified, Emergency Medicine'
Medical Legal Consultant

From: Joseph H Talley
Sent: Thursday, December 02, 2004 1:18 PM

- Portenoy once gave a patient the equivalent of 35,000mg of oral morphine a day, (which would have been 2,333 of the 15 mg tablets) but the patient wasn't actually swallowing it (actually 7,000mg through a morphine pump). I got it off a post-graduate education tape he and others made, not from a written paper. I am sure he has it written up, since I have heard him refer to it more than once. The patient was a cancer patient, and the tape showed him walking up and down the hall perfectly alert and normal, dragging his IV pole along with him as I recall.

Joe Talley, M.D.

Note: The following table is adapted from Principles of Analgesic Use in the Treatment of Acute Pain and Cancer Pain 4th Ed. Chicago: American Pain Society, 1999. Note that morphine is the reference drug against which other opioids are compared.

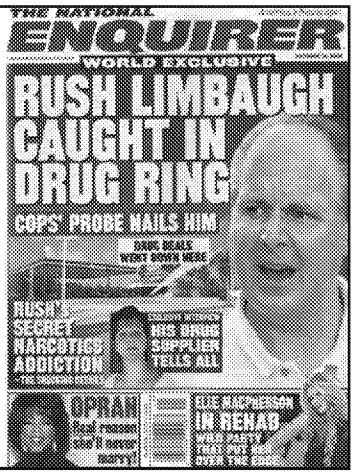
Equianalgesic Doses of Opioid Analgesics

ORAL/RECTAL DOSE	ANALGESIC	PARENTERAL DOSE (MG)
30-60	Morphine	10
7.5-8	Hydromorphone (Dilaudid)	1.5
20	Oxycodone	(not available)
see below	Methadone	see below
4 acute, 1 chronic	Levorphanol (Levo -Dromoran)	2 acute, 1 chronic
(not available)	Fentanyl	0.1 (100mcg)
see below	Fentanyl (transdermal)	see below
300	Meperidine (not recommended)	75
200	Codeine (not recommended)	120
20	Hydrocodone	(not available)
Not recommended	Propoxyphene	(not available)

Transdermal Fentanyl (fentanyl patch) - 50 mcg/h patch = Morphine 100mg PO/24 h = 16 mg PO q4h = 1.4 mg/h IV.

Methadone - is an excellent choice for opioid rotation. Where other opioids can be converted based on a fixed ratio, the starting methadone dose decreases proportionately as the dose of the previous drug increases. Put another way, the morphine:methadone ratio changes as the morphine dose increases. Calculate the equianalgesic dose using the following method, then reduce the calculated dose by 25-50% to determine the starting dose. The following table shows PO morphine:PO methadone. <90 mg MS 4:1, 91-300 mg MS 8:1, 301-600 mg MS12:1

- Is Rush Limbaugh an Addict?



DSM-IV "Substance Use Disorder"

A maladaptive pattern of substance use leading to significant impairment or distress as manifested by 3 or more of the following 9 symptoms:

- Need for markedly increased doses to achieve effect
- Diminished effect with same dose
- Withdrawal syndrome
- Taking substance to relieve or avoid withdrawal symptoms
- Dose escalation or prolonged use
- Persistent desire or unsuccessful efforts to cut down or control substance use
- Excessive time spent obtaining, using, or recovering from use of the substance
- Activities abandoned because of substance use
- Use despite harm

The American Academy of Pain Medicine, the American Pain Society, and the American Society of Addiction Medicine recognize the following definitions and recommend their use:

I. Addiction is a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include one or more of the following: impaired control over drug use, *compulsive use*, *continued use despite harm*, and craving.

II. Physical Dependence is a state of adaptation that is manifested by a drug class specific withdrawal syndrome that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist.

III. Tolerance is a state of adaptation in which exposure to a drug induces changes that result in a diminution of one or more of the drug's effects over time.

FSMB Guideline Definitions:

- Addiction—Addiction is a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include the following: impaired control over drug use, craving, compulsive use, and continued use despite harm. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and are not the same as addiction.
- Physical Dependence—Physical dependence is a state of adaptation that is manifested by drug class-specific signs and symptoms that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist. Physical dependence, by itself, does not equate with addiction.
- Tolerance—Tolerance is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce a specific effect, or a reduced effect is observed with a constant dose over time. Tolerance may or may not be evident during opioid treatment and does not equate with addiction.

Is Rush Limbaugh an Addict?

- Physical Dependence
- Tolerance
- Psychological Dependence
- Addiction

Two other issues:

- Iatrogenic Addiction
- DSM v. Consensus/FSMB definition

Who Are We Looking For?

- Dated: the physician whose knowledge is not current or adequate to the job.
- Duped: the physician who is repeatedly scammed.
- Disabled: the impaired or dysfunctional physician.
- Dishonest: the greedy, desperate, or otherwise criminally inclined.

Dishonest:

- "Pill Mill" operations: high volume, low overhead, odd hours, out-of-town patients, very poor records, everyone gets the same "cocktail" prescription, significant cash business. Subjective and objective bad faith.
- Goals: prison and revocation.
- There are very few of these, fortunately.

Disabled/Dysfunctional:

- Physicians become substance abusers at no less a rate than the general population.
- Impairment may be by chemical abuse, disease process, aging, medication, mental illness, or personality disorder (e.g. the infamous "borderline personality")
- Behavior may appear to be duped, dishonest, or "caving in" to patient pressure, but is a product of disability. Full residential examination by competent addictionologists is required (e.g. Rogers, Rush, Talbott, Sierra Tucson, Hazelden, etc.).
- Goal: rehabilitation by treatment, OR protection of the public by removal of DEA registration (esp. in personality disorder cases).

Duped:

- Thexton's Rule: every physician in clinical practice will be scammed at some point in his/her career.
- Some scammers are very skilled, use the internet and other networking techniques.
- Physicians who are repeatedly duped need to ask themselves: "Why me?"
- Physicians prescribing CS for chronic pain must have a personality which allows them to keep an adequate index of suspicion, and confront their patients.
- Goal: rehabilitation through education (and therapy).

Dated:

- Physicians receive no training in chronic pain management in medical school or residency.
- They fear investigation and loss of professional reputation/career more than death, divorce, or prison; this leads them to fear prescribing CS for chronic pain.
- Undertreatment of pain is a major public health issue, and we must encourage more prescribing for appropriate patients.
- Goal: rehabilitation through education. Discipline seldom required.

Profile of Docs in Trouble:

- Not ABMS Board-Certified. *www.abms.org*
- Solo practitioner.
- Marginal in the professional community: no hospital privileges, not respected by peers, not active in local medical society.
- Older, close to retirement or already semi-retired.
- None of these criteria is completely predictive, or required: there are exceptions to almost every rule!

❖Specialized CME for rehabilitation:

- ❖ Case Western Reserve University: 40+ hrs.
- ❖ University of Medicine & Dentistry of NJ: 25 hour course on DVD for home study, proctored exam.
- ❖ University of South Florida & Vanderbilt University: 20+ hrs.
- ❖ Other occasional offerings.

Investigative Techniques

- Setting goals as early as reasonably possible
- Task Force approach: working with other agencies: both investigative and prosecutorial: pharmacy board, police, DA, HHS/IG, FBI, DEA, US Attorney)
- Undercover patients: essential in dishonesty cases (use recording devices)

Chart Issues

- Cancer & other terminal cases; palliation the only goal.
- Non-terminal cases: function is the major goal.
- What do I look for in a chart?
  - Pain adequately described, classified, measured [PQRST: next slide]. Changes adequately described, classified, measured (consistent use of a pain scale).
  - Appropriate history and physical examination. Prior records or charted contact with previous providers. Appropriate studies.
  - A diagnosis.
  - Functional objectives: ADL and/or occupational. ("Decrease pain" is *NOT* a FUNCTIONAL objective.)
  - Alternatives to opioids attempted with responses documented.
  - Referrals/consultations: reports received and responses documented.
  - Med Sheet in the chart, used and checked consistently.

Pain History

- "PQRST"*
  - Provocative/palliative factors (e.g., position, activity, etc.)
  - Quality (e.g., aching, throbbing, stabbing, burning)
  - Region (e.g., focal, multifocal, generalized, deep, superficial)
  - Severity (e.g., average, least, worst, and current)
  - Temporal features (e.g., onset, duration, course, daily pattern)
- Medical history
  - Existing comorbidities and AODA history in pt./family
  - Current medications

*Valley MA. Pain measurement. In: Raj PP. Pain Medicine. St. Louis, MO: Mosby, Inc; 1996:36-46.

- The challenging patient: current or historic abuser/addict, often uninsured and not employed. Distinguish between dependence and addiction. In these charts, I look for:
  - The "pain contract" (Medication Agreement) Elements:
    - One doctor, one pharmacy; consider including pharmacist in signing, and collaborating in care.
    - No early refills. [But: consider pseudoaddiction]
    - Frequent checkups, short Rx refill periods to start.
    - Family/caretakers involved at all levels.
    - Frequent (at first) unpredictable urine screens.
    - Compliance leads to continuance in care.
  - Adequate index of suspicion ("healthy skepticism"). Believing the patient is not the same as thinking the patient is always right, or has the right to self-prescribe.
  - Is the patient using drugs to live his life, or living his life to use drugs?
  - End opioid therapy or discharge repeatedly non-compliant patient.

What I Look For (con't):

- Drug therapy considerations:
  - Long acting, on scheduled dosing
  - Consider methadone
  - Short-acting PRN meds only for flare-up pain
  - Consultations/collaboration with pharmacist

Physicians Who Dispense

- DEA Diversion Investigators
- Inventories
- Samples
- Records of receipt, dispensing, disposal
- Secure storage
- Logs/chart entries
- State CS permit/registration

Working with the Expert

- Qualifications: board certification www.abms.org
- Opiophobia and other disqualifiers
- Literature and other documentation of current standard of care (see handouts)
- The "respectable minority" and what they are saying about prescribing opioids for chronic pain
- Knowledge of the following:

Symptomatic Treatments for Chronic Pain*

- Pharmacotherapy
- Rehabilitative approaches
- Psychological approaches
- Anesthesiologic approaches (blocks etc.)
- Surgical approaches
- Neurostimulatory approaches (TENS)
- Complementary and alternative approaches
- Lifestyle changes

*Joint Commission on Accreditation of Healthcare Organizations. Pain management today. In: Pain Assessment and Management: An Organizational Approach. Joint Commission in Accreditation of Healthcare Organizations. Oakbrook Terrace, IL; 2000:1-6.

Pharmacotherapy for Pain

Categories of analgesic drugs *

- Opioid analgesics (synthetics, semi-synthetics, opiates)
- Nonopioid analgesics (NSAIDS, Acetaminophen)
- Adjuvant analgesics (neuromodulators, SSRI's, anti-convulsants, benzos)
- Headache medications (sumatriptan)

*McCaffery M, Portenoy RK. Overview of three groups of analgesics. In: McCaffery M, Pasero C. Pain: Clinical Manual. 2nd ed. St. Louis, MO: Mosby, Inc; 1999:108-128.

Aberrant Drug-related Behaviors—The Model*

- Probably more predictive of addiction or diversion:
  - Selling prescription drugs
  - Prescription forgery
  - Stealing or borrowing another patient's drugs
  - Injecting oral formulation
  - Obtaining prescription drugs from non-medical sources
  - Concomitant abuse of related illicit drugs
  - Multiple unsanctioned dose escalations
  - Recurrent prescription losses

* Passik SD, Whitcomb L, Kirsch K, et al. Pain outcomes as assessed with a pain assessment and monitoring tool in chronic non-malignant pain patients treated with opioids: results of final analyses. Paper presented at: The International Conference on Pain and Chemical Dependency; June 6-8, 2002; New York, NY.

Aberrant Drug-related Behaviors—The Model, con't*

- Probably *less* predictive (or indicative of pseudoaddiction):
  - Aggressive complaining about need for higher doses
  - Drug hoarding during periods of reduced symptoms
  - Requesting specific drugs
  - Acquisition of similar drugs from other medical sources
  - Unsanctioned dose escalation 1 – 2 times
  - Unapproved use of the drug to treat another symptom
  - Reporting psychic effects not intended by the clinician

* Passik SD, Whitcomb L, Kirsch K, et al. Pain outcomes as assessed with a pain assessment and monitoring tool in chronic non-malignant pain patients treated with opioids: results of final analyses. Paper presented at: The International Conference on Pain and Chemical Dependency; June 6-8, 2002; New York, NY.

"Pseudoaddiction"*

- Pattern of drug-seeking behavior of pain patients receiving inadequate pain management that can be mistaken for addiction
  - Cravings and aberrant behavior
  - Concerns about availability
  - "Clock-watching"
  - Unsanctioned dose escalation
- Resolves with re-establishing analgesia

* Weissman DE, Haddox JD. Opioid pseudoaddiction — an iatrogenic syndrome. Pain. 1989;36:363-366.

E-8.19 Self-Treatment or Treatment of Immediate Family Members

- Physicians generally should not treat themselves or members of their immediate families. Professional objectivity may be compromised when an immediate family member or the physician is the patient; the physician's personal feelings may unduly influence his or her professional medical judgment, thereby interfering with the care being delivered. Physicians may fail to probe sensitive areas when taking the medical history or may fail to perform intimate parts of the physical examination. Similarly, patients may feel uncomfortable disclosing sensitive information or undergoing an intimate examination when the physician is an immediate family member. This discomfort is particularly the case when the patient is a minor child, and sensitive or intimate care should especially be avoided for such patients. When treating themselves or immediate family members, physicians may be inclined to treat problems that are beyond their expertise or training. If tensions develop in a physician's professional relationship with a family member, perhaps as a result of a negative medical outcome, such difficulties may be carried over into the family member's personal relationship with the physician.
- Concerns regarding patient autonomy and informed consent are also relevant when physicians attempt to treat members of their immediate family. Family members may be reluctant to state their preference for another physician or decline a recommendation for fear of offending the physician. In particular, minor children will generally not feel free to refuse care from their parents. Likewise, physicians may feel obligated to provide care to immediate family members even if they feel uncomfortable providing care.
- It would not always be inappropriate to undertake self-treatment or treatment of immediate family members. In emergency settings or isolated settings where there is no other qualified physician available, physicians should not hesitate to treat themselves or family members until another physician becomes available. In addition, while physicians should not serve as a primary or regular care provider for immediate family members, there are situations in which routine care is acceptable for short-term, minor problems.
- Except in emergencies, it is not appropriate for physicians to write prescriptions for controlled substances for themselves or immediate family members. (I, II, IV) Issued June 1993.

Criminal Self-prescribing:

§961.38(5), Wis. Stats.: "No practitioner shall prescribe, orally or in writing, or take without a prescription, a controlled substance included in schedule I, II, III or IV for the practitioner's own personal use."

[From Uniform Controlled Substances Act]

Other states: Hawaii, Nevada, Washington

PRESCRIBING SOC RESOURCES

The following are important and current (2004) resources for prescribers of controlled substances:

- "Prescription Pain Medications: Frequently Asked Questions" is a 48 page booklet authored by leading pain specialists, with DEA cooperation and approval, but now withdrawn by DEA. http://www.doctordeluca.com/Library/WOD/DEA-Pain&PolicyPainMedFAQ04.pdf
- "Model Policy for the Use of Controlled Substances for the Treatment of Pain," by the Federation of State Medical Boards. (6 pages.) www.fsmb.org
- "Guidelines for the Assessment and Management of Chronic Pain" is a 30 page booklet by the Wisconsin Medical Society's Task Force on Pain Management. www.wisconsinmedicalsociety.org/uploads/wmj/ACFC7.pdf

From: Greg Staviski [mailto:athena1@mchsi.com]
Sent: Friday, December 24, 2004 2:08 PM
To: NADDI Rxnews
Subject: Deputy's Mother Commits Suicide due to Pain on December 18

To NADDI Friends:

My colleague and fellow Law Enforcement Officer's mother committed suicide on Saturday due to pain. She was 45, a dedicated mom, wife, and had intractable pain.

The current conversation brought this issue to a very personal level when my Chief called me to let me know. Several of my classmates from rookie school and I attended the funeral on Tuesday December 21, 2004. She had seen a "pain specialist" at Mayo Clinic who told her that she was going to have to live with the pain and he wouldn't be prescribing any further narcotics.

She committed suicide two days later.

I'm not offering any real "point" here but to say I hope that after all the dust settles, people who really need narcotics to ease their suffering will be able to get them and those who shouldn't be getting them get swift punishment.

Warmly and Wishing my friends at NADDI a Merry Christmas

Greg Staviski
Deputy Sheriff, Santa Rosa County FL

Dispensing of Controlled Substances for the Treatment of Pain

published by DEA in the *Federal Register*, November 16, 2004 (FR Doc 04-25469):

"For a physician to prepare multiple prescriptions on the same day with instructions to fill on different dates is tantamount to writing a prescription authorizing refills of a schedule II controlled substance."

Arthur Thexton
Prosecuting Attorney
Wisconsin Department of Regulation & Licensing
Telephone: 608-266-9814
FAX: 608-266-2264
arthur.thexton@drl.state.wi.us

Related Articles

U. S. Department of Justice
Drug Enforcement Administration

www.dea.gov

Washington, D.C. 20537

JAN 31 2003

Howard A. Heit, M.D., F.A.C.P., F.A.S.A.M.
8316 Arlington Boulevard, Suite 232
Fairfax, Virginia 22031

Dear Dr. Heit:

This is in response to your correspondence dated January 15, 2003, regarding the Drug Enforcement Administration's (DEA) policy concerning the legality of a practitioner issuing several Schedule II prescriptions on the same date for the same medication for a stable patient (one for immediate use, one not to be filled before 30 days and one not to be filled before 60 days).

The DEA regulations do not prohibit a practitioner from issuing more than one prescription at a time. If, in keeping with the practitioner's professional medical judgment, multiple prescriptions are issued at one time, each must bear the actual date that the prescriptions were issued and signed as well as directions for dispensing. For example, if three prescriptions, each for a 30-day supply, are issued on January 9, 2003, each prescription must be dated January 9, 2003. In addition, the prescriptions to be filled at later dates must include directions for the dispensing pharmacist such as, "do not dispense before February 9, 2003," and "do not dispense before March 9, 2003." Although Title 21 of the Code of Federal Regulations, Section 1306.12 (21 CFR 1306.12) prohibits the refilling of a prescription for a Schedule II controlled substance, the DEA does not consider multiple prescriptions in the scenario outlined above as refills, and has authorized this practice **provided** that it is not in violation of the laws of the state in which the practitioner is licensed.

Although the DEA does not restrict the frequency or quantity of prescriptions, state medical/pharmacy boards or insurance providers may impose some limit on the prescribing or dispensing of controlled substance medications. The practitioner may wish to contact these parties for information regarding any limits they impose on the quantity of medication that may be prescribed and dispensed.

The DEA appreciates your efforts in informing other practitioners of DEA policies on the handling of controlled substances. The above cited regulation and information regarding DEA's Diversion Control Program are available on our web site at www.DEAdiversion.usdoj.gov. Should you have additional questions, please contact Fred H. Shiel, R.Ph., at (202) 307-7295.

Sincerely,

Patricia M. Good, Chief
Liaison and Policy Section
Office of Diversion Control

BEFORE THE

BOARD OF MEDICAL EXAMINERS

STATE OF OREGON

In the Matter of PAUL ANDRE BILDER, M.D. LICENSE NO. MD 10160	STIPULATED ORDER

1.

The Board of Medical Examiners (Board) is the state agency responsible for licensing, regulating and disciplining certain health care providers, including physicians, in the State of Oregon. Paul Andre Bilder, M.D. (Licensee) is a licensed physician in the State of Oregon.

2.

The Board conducted an investigation into complaints concerning Licensee and his care of certain patients. On March 19, 1999, the Board proposed taking disciplinary action pursuant to ORS 677.205 against Licensee for acts and conduct alleged to violate the Medical Practices Act. The acts and conduct alleged to violate the Medical Practices Act are:

2.1. Licensee provided primary medical care to Patient A, an elderly male patient that spent his final days at home under the care of hospice. Patient A had multiple serious health conditions, including metastatic cancer of the prostrate, a history of lung cancer, and increasing skeletal pain secondary to metastatic disease. On February 15, 1998, Patient A began experiencing increasing muscular skeletal pain. Licensee treated this pain with Tylenol. The pain increased in March, and Licensee

treated the pain with Darvocet N 100. According to Licensee, Patient A was admitted to Mercy Medical Center on March 18, 1998 for lower GI bleed, constipation and pain medicine side effects. On March 22nd, Patient A's pain increased and was treated with Oxycontin twice a day. Hospice care began while Patient A was still in the hospital. On March 24th, Patient A was discharged from Mercy Medical Center to Mercy Care Center Nursing and then to his home on March 31st. On April 6th, a hospice nurse informed Licensee that Patient A had breakthrough pain, required a Foley catheter, stronger pain medication, and an anti-anxiety medication. Licensee refused placement of a Foley catheter on the basis that it might induce a urinary tract infection. Licensee ordered substantially inadequate amounts of pain medication. Patient A died on April 7, 1998.

2.2 Patient B, an 84 year old male, was under hospice care, and had a history of metastatic lung cancer and urinary incontinence. On or about January 2, 1997, the patient's family requested placement of a Foley catheter on the patient due to his incontinence. Unable to contact Licensee, a hospice nurse placed a Foley catheter on Patient B. After being notified by the hospice nurse, Licensee directed that the Foley catheter be removed and that the patient use diapers, contrary to the expressed wishes of the patient and his family. The hospice nurse also requested a dose of Roxanol, an oral morphine preparation, of 5 mg to 20 mg every four hours for treatment of pain. Licensee believed this was excessive and gave a verbal order of only 0.25 cc every four hours and Tylenol for temperature greater than 102 degrees. Patient B died at about 6:45 p.m. that evening.

2.3 Patient C, a 35 year old female suffering from a history of COPD with a component of reactive airways disease as well as other conditions, was admitted to

Mercy Medical Center on September 16, 1993 for exacerbation of her COPD and reactive airways disease. Patient C was intubated, mechanically ventilated and placed on sedatives and pain medication. On September 20th, Licensee discontinued sedatives and pain medication for Patient C. A short time thereafter, Patient C became increasingly restless, had increased wheezing, had a decrease in saturation, and was observed to be fighting the ventilator. Licensee refused a request for sedatives and pain control medications. Patient C subsequently extubated herself, with desaturation ranging from 78% to 88%. Licensee was informed of this condition and was asked whether he would come in to reintubate the patient; he asked for a status report on the patient. Three hours after the patient extubated herself, she required re-intubation by an emergency room physician. Licensee then ordered a paralytic agent, but did not order the use of a sedative.

2.4 Patient D, a 63 year old woman, suffered from multiple health conditions, including severe COPD, adult onset diabetes and cor pulmonale. She was admitted to Mercy Medical Center for acute respiratory failure. Licensee ordered continuous IPPB treatments with 0.125 ccs of a Proventil solution every 15 minutes. Licensee did not use CPAP, biPAP or non-invasive treatment for respiratory failure. The patient was ultimately intubated. Licensee was asked to order morphine to treat the patient's anxiety, but he refused. Licensee ordered paralytic agents for ventilator tolerance without any sedatives or pain medication.

2.5 Patient E, a 82 year old male, suffered from dyspnea secondary to congestive heart failure, with a history of diabetes, hypertension, hyperlipidemia and was "Do Not Resuscitate" (DNR). This patient was admitted to Mercy Medical Center on December 28, 1996, for congestive heart failure related to myocardial infarction.

Patient E had labored respiration, and commented to the nurse that "I just can't breathe and I'm getting tired." Licensee declined to administer morphine or similar pain medications to the patient. Patient E was noted to have increasing desaturation, was becoming increasingly agitated, and had an increased respiratory rate and heart rate. Licensee ordered Lasix for the patient, but the patient's heart rate continued to increase along with his respiration rate, while the oxygen level in his bloodstream decreased. Nevertheless, Licensee repeatedly refused to order treatment with morphine. Patient E was subsequently treated, stabilized and discharged several days thereafter by his regular physician.

2.6 Patient F, a 33 year old male with a past history of pneumonia requiring intubation, IV drug use, depression, hypertension and chronic lower back pain was admitted to Mercy Medical Center on January 15, 1998, with severe pneumonia associated with a hypoxemia. Licensee elected to intubate the patient. Attempts to nasally intubate the patient caused some bleeding and finally involved the use of physical restraint. By not using anxiolytics and narcotics during a procedure that was painful, Licensee put the patient at increased risk of further oxygen desaturation, aspiration, and failed intubation. Additionally, forcibly intubating Patient F without using anxiolytics and narcotics while he was in an agitated or combative state also put the medical staff and the patient at risk of injury.

3.

Licensee and the Board desire to settle this matter by the entry of this Stipulated Order. Licensee understands that he has the right to a contested case hearing under the Administrative Procedures Act (chapter 183), Oregon Revised Statutes and fully and finally waives the right to a contested case hearing and any appeal therefrom by the

signing of and entry of this Order in the Board's records. Licensee stipulates that there is evidence from which the Board could find that Licensee engaged in the conduct described in paragraph 2 and that this conduct violates ORS 677.190(1), unprofessional or dishonorable conduct, as defined in ORS 677.188(4)(a) and (b); and ORS 677.190(14), gross negligence or repeated negligence in the practice of medicine.

4.

Licensee and the Board agree to resolve this matter by the entry of this Stipulated Order subject to the following conditions:

4.1 Licensee, having already enrolled in the Physician's Evaluation Education Renewal program (PEER), shall successfully complete the program.

4.2 Licensee will enroll in and complete a course, approved in advance by the Investigative Committee, that focuses on physician/patient communications.

4.3 Licensee shall continue psychiatric care with Dr. Ronald L. Hofeldt , or another psychiatrist approved in advance by the Investigative Committee. Licensee shall meet at least monthly with his treating psychiatrist.

4.4 The treating psychiatrist shall provide written quarterly reports to the Board by the first day of each month of each quarterly Board meeting.

4.5 Should Licensee be absent from this state for any period of time which would interfere with meeting the requirements of these terms, Licensee must request approval for alternative means of satisfying those terms.

4.6 The above-referenced conditions shall continue in full force and effect without opportunity for amendment, except for clear error in drafting, for 12 months following entry of this Order. If, after the passage of the 12 month period,

BEFORE THE

BOARD OF MEDICAL EXAMINERS

STATE OF OREGON

In the Matter of PAUL ANDRE BILDER, MD LICENSE NO. MD10160	))))))	STIPULATED ORDER

1.

The Board of Medical Examiners (Board) is the state agency responsible for licensing, regulating and disciplining certain health care providers, including physicians, in the State of Oregon. Paul Andre Bilder, MD (Licensee) is a licensed physician in the State of Oregon.

2.

The Board proposed to take disciplinary action pursuant to ORS 677.205 against Licensee for violations of the Medical Practices Act, to wit: ORS 677.190(1)(a) unprofessional or dishonorable conduct, as defined in ORS 677.188(4)(a); ORS 677.190(14) gross or repeated acts of negligence; ORS 677.190(18) willfully violating any rule or board order adopted by the Board; and ORS 677.190(25) prescribing controlled substances without a legitimate medical purpose, or prescribing controlled substances without following accepted procedures for examination of patients, or prescribing controlled substances without following accepted procedures for record keeping or without giving the notice required under ORS 677.485.

3.

The acts and conduct alleged to violate the Medical Practices Act are:

3.1 On September 1, 1999, the Board entered into a Stipulated Order with Licensee which imposed conditions on his license. The Board's review of the care provided to Patient A and Patient B during the current investigation was found to be similar to conduct in the previous investigation.

4.

Licensee wishes to seek amendment or termination of these conditions, Licensee may petition the Board in writing. The Board's Investigative Committee may inquire into the request and may, in its sole discretion, grant or deny the petition.

4.7 Licensee stipulates and agrees that any violation of the terms of this Order shall be grounds for further disciplinary action under ORS 677.190(18).

IT IS SO STIPULATED this 9th day of August, 1999.

Paul A. Bilder MD
Paul Andre Bilder, MD

IT IS SO ORDERED this 1ST day of September, 1999.

BOARD OF MEDICAL EXAMINERS
State of Oregon

George A. Porter, MD
George A. Porter, MD
Chairman of the Board

Licensee and the Board desire to settle this matter by the entry of this Stipulated Order. Licensee understands that he has the right to a contested case hearing under the Administrative Procedures Act (chapter 183), Oregon Revised Statutes and fully and finally waives the right to a contested case hearing and any appeal therefrom by the signing of and entry of this Order in the Board's records. Licensee stipulates that he engaged in the conduct described in paragraph 3 and that this conduct violates: ORS 677.190(1)(a) unprofessional or dishonorable conduct, as defined in ORS 677.188(4)(a); ORS 677.190(14) gross or repeated acts of negligence; ORS 677.190(18) willfully violating any rule or board order adopted by the Board.

5.

Licensee and the Board agree to resolve this matter by the entry of this Stipulated Order. Licensee is placed on probation for a period of ten (10) years subject to the following conditions:

5.1 Licensee is reprimanded.

5.2 Licensee shall report in person to the Board at each of its regularly scheduled quarterly meetings at the scheduled times for a probationer interview unless ordered to do otherwise.

5.3 Licensee shall enroll in and complete the Board's Appropriate Prescribing Workshop within ten (10) months from the date the Board Chair signs this Order.

5.4 Licensee shall continue psychiatric care with a psychiatrist approved in advance by the Board's Medical Director. Licensee shall continue to meet at least monthly with his treating psychiatrist. The treating psychiatrist shall provide written quarterly reports to the Board by the first day of January, April, July, and October.

5.5 Licensee, in conjunction with the Oregon Medical Association's PEER program and a consulting psychiatrist, has developed guidelines under which Licensee has agreed to practice. The Board approves these guidelines and Licensee agrees to follow these guidelines which include, but are not limited to, the following conditions:

a) For any patient of Licensee's who has been diagnosed with a terminal condition, Licensee shall offer to transfer their care to another physician. For those terminally ill patients who remain under the care of Licensee, if pain

becomes an issue for any of these patients, the pain aspect of their care shall be expediently transferred to another physician.

b) Licensee shall no longer treat patients involved in hospice care.

c) Licensee shall transfer patients meeting the conditions of sections a & b above to other internal medicine physicians or other qualified practitioners. The patient transfer shall be accomplished within fourteen (14) days from the date the patient develops a qualifying condition.

5.6 Licensee, with the assistance of PEER and a consulting psychiatrist, are working on a policy outlining the procedures Licensee will use to inform terminal patients of their options related to care and pain management, as well as transfer to other physicians. This policy will be submitted to the Board within thirty (30) days of the date this Order is signed by the Board Chair. The Board's Medical Director may require changes in the policy and will give the final approval prior to the policy being accepted as part of this Order. Licensee and the Board have identified the following areas which will be addressed in the policy:

a) Licensee's procedure for informing patients covered by this Order.

b) Licensee's procedure for informing patients who wish to remain under Licensee's care for non-pain care that the pain management aspect of their care will be provided by another physician. Licensee will not interfere with the care provided by the physician handling a patient's pain management.

c) Licensee's plan will include safeguards to ensure that patients are not made to feel uncomfortable or abandoned by Licensee if their care is transferred to another physician.

5.7 Licensee and PEER will establish a system for reviewing care and compliance with the aforementioned policy for terminal patients and patients who have been transferred to other physicians. PEER will provide quarterly reports to the Board.

5.8 The Board's Compliance Officer shall have access to Licensee's office/clinic, including immediate access to patient records, for inspection purposes to ensure Licensee's compliance with the terms of this Order. This inspection may occur at any time Licensee's office is open during normal business hours.

5.9 Should Licensee be absent from this state for any period of time which would interfere with meeting the requirements of these terms of probation, Licensee shall request approval for alternative means of satisfying those terms. Failure to receive Board approval may result in an extension of this probation for a time equivalent to time Licensee has been absent from the State or other action as may be deemed appropriate.

5.10 Licensee shall obey all federal, state and local laws and rules governing the practice of medicine in the state of Oregon.

5.11 Licensee stipulates and agrees that any deviation or violation from the terms of this Order shall be grounds for further discipline pursuant to ORS 677.190(18).

IT IS SO STIPULATED this 3 day of March, 2003.

Paul Andre Bilder MD
PAUL ANDRE BILDER, MD

IT IS SO ORDERED this 17th day of April, 2003.

BOARD OF MEDICAL EXAMINERS
State of Oregon

JUDITH L. RICE
Board Chair

Journal of Law, Medicine & Ethics
Spring, 2001

PAIN MANAGEMENT AND PROVIDER LIABILITY: NO MORE EXCUSES.

Barry R. Furrow

Pain[1] is undertreated in the American health-care system at all levels: physician offices, hospitals, long-term care facilities.[2] The result is needless suffering for patients, complications that cause further injury or death, and added costs in treatment overall. The health-care system's failure to respond to patient pain needs corrective action. Excuses for such shortcomings are simply not acceptable any longer.

Physicians have long been accused of poor pain management for their patients.[3] The term "opiophobia" has been coined to describe this remarkable clinical aversion to the proper use of opioids to control pain.[4] If the professional mandate of the health-care professional is to relieve suffering, then physicians are falling far short of their obligations[5] by accepting myths about the use of opioids in the face of evidence to the contrary.[6]

The possible reasons for health-care providers' failures to properly manage pain are many. First, physicians are poorly educated in medical school about narcotics and proper pain management, and they remain ignorant in practice about appropriate treatment choices for pain management,[7] often rapidly absorbing professional norms that simply reflect a culture hostile to drug use.[8] Second, threats of legal action loom large in providers' vision: criminal prosecution for use of controlled substances; sanctions involving the loss of hospital staff privileges for use of opiates; medical licensing board disciplinary action; and so on. Uncertainty about legitimate opioid use, coupled with a regulatory system that threatens sanctions, intimidates physicians.[9] Third, patients, worried about tolerance and addiction to the opioids, receive little adequate information or education by providers.[10] Patients suffer unnecessary pain as a result.[11] Fourth, lack of insurance coverage may deny patients access to costly long-term pain management with its multiple modalities of treatment.[12]

Scholars have examined many of these barriers -- restrictions on insurance reimbursement,[13] Medicare and Medicaid limits,[14] and criminal prosecutions -- and their effect on the use of effective tools for pain control.[15] It is clear that the legal and regulatory environment is a complicated one, with cross-currents that make it difficult for physicians to offer optimal care. What is missing is an external source of norms that articulate the values of pain relief and impose a penalty on providers for their shortcomings. Such a source of pressure can counteract the fears of criminal prosecution and the pressures of both inertia and restrictions on reimbursement that push physicians, hospitals, managed care organizations, and nursing homes to undertreat pain. Tort liability is a powerful external threat, and it can work in tandem with other constructive pressures in the environment to improve provider management of patient pain.

The threat of a malpractice suit for undertreatment of pain is presently quite low. Few judicial decisions discuss pain management and undertreatment. Pain as a component of a tort suit shows up primarily in pain and suffering awards for a physician's negligent treatment or diagnosis of a patient that leads to physical harm and accompanying pain; workers compensation claims for pain treatments; or a component of emotional distress claims. If, however, a physician's treatment of the patient's illness meets the medical standard of care, then the pain attendant on the normal course of illness has typically not been the object of tort damages. What is needed is recognition that the standard of care in treating patients includes pain management as much as it does treatment of the disease.

Treatment and management of pain by both physicians and institutional providers can be improved by the threat of tort litigation, which would spotlight providers' failures to comply with an emergent standard of proper pain management. This threat of litigation can be a powerful incentive to change medical practices. This article will analyze existing and emerging liability theories and doctrines that should have an impact on the attitudes of physicians and institutional providers toward pain management.

I. THE NATURE OF PAIN: TOUGHING IT OUT

Pain is often viewed as an inevitable part of illness, as a necessary adjunct to disease and its treatment. Too often physicians simply force patients to tough it out, to cope with pain that is unnecessary and debilitating. Patients may also share an attitude that pain is normal and should simply be endured, although this is in contrast to patients with advanced diseases, who welcome pain management for their symptoms.[16] Most pain can be treated and relieved, even though sadly it is too often untreated or poorly managed.[17]

A. Categories of pain

Pain is traditionally divided into acute and chronic pain. Acute pain may be the result of surgery, dental work, burns, or other somatic damage that results in pain of limited duration. Chronic pain may be divided into cancer pain and nonmalignant pain. For nonmalignant pain, palliative medicine is the therapeutic response, defined as "the study and management of patients with active, progressive, far-advanced disease for whom the prognosis is limited and the focus of care is the quality of life."[18] Such pain is also often termed "intractable," to mean any condition or situation that is unmanageable or untreatable.[19] While the disease or condition may be untreatable, the pain and symptoms most often can be treated. Chronic pain is usually viewed as appropriately treatable by opioid analgesics on a long-term basis.[20]

Cancer pain is one of the largest categories of pain. Millions of cancer patients suffer pain that could be relieved and managed by proper treatment. One estimate is that more than 90 percent of cancer pain can be controlled with available treatment options.[21] Analgesic drugs, in particular, are an effective approach to managing cancer pain; these include aspirin, codeine, morphine, and their substitutes.

The elderly, particularly in nursing homes, suffer high levels of pain -- chronic and nonmalignant in many cases -- that is poorly managed up to 70 percent of the time. According to clinical practice guidelines on the management of chronic pain in older persons, "For some conditions, chronic pain is defined as pain that exists beyond an expected time frame for healing. For other conditions, it is well recognized that healing may never occur. In many cases, chronic pain is understood as persistent pain that is not amenable to routine pain control methods. Because there are many differences in what may be regarded as chronic pain, the definition remains flexible and related to specific diagnoses or cases."[22]

The standard of practice for pain management is well articulated for cancer pain, for surgical pain, and for nonmalignant chronic pain. But medical practice has been slow to adopt this standard due to fear of addiction and a multiplicity of other factors.[23]

B. Proper pain management

Pain management is defined in the most recent Joint Commission on Accreditation of Healthcare Organizations (JCAHO) guidelines as "a comprehensive approach to the needs of patients, residents, clients, or other individuals served who experience problems associated with acute or chronic pain."[24] Proper assessment of pain, based on patient self-reporting, is at the heart of any organizational approach to pain management. Pain comes in many forms, but treatment of so-called "intractable" pain follows a generally agreed-upon pyramid of treatment, in which the non-steroidal anti-inflammatory drugs (NSAIDs) and other drugs in combination with patient training come first, and opioids are the final and effective treatment for all forms of pain that fail to respond to milder drugs. As Joranson and colleagues state, "the use of opioids in the class of morphine is the cornerstone of pain management."[25] Yet patients and clinicians continue to be unduly concerned about addiction. Joranson and colleagues comment that "[h]ealth care professionals may be reluctant to prescribe, administer, dispense, or stock controlled substances for fear of causing addiction or contributing to the drug abuse problem."[26] Addiction is viewed as an evil to be avoided even when its likelihood is low, leaving patients to a stoic absorption of pain that most cannot achieve. Recent studies confirm that abuse of opioid analgesics has remained low in spite of increases in their medical use.[27]

Failure to properly manage pain -- to assess, treat, and manage it -- is professional negligence.[28] The problem from a malpractice perspective is one of establishing a standard of care based on a clear practice in favor of sophisticated pain management. The current versions of the ethical principles governing clinical practice -- the Hippocratic Oath and the Code of Ethics of the American Medical Association (AMA) -- and the statements of medical leaders do articulate the duty to relieve suffering. For example, the AMA's Code of Medical Ethics states in pertinent part, "[p]hysicians have an obligation to relieve pain and suffering and to promote the dignity and autonomy of dying patients in their care. This includes providing effective palliative treatment even though it may foreseeably hasten death."[29] Nurses likewise are admonished to "use full and effective doses of pain medication for the proper management of pain in the dying patient. The increasing titration of medication to achieve adequate symptom control, even at the expense of life, thus hastening death secondarily, is ethically justified."[30] But medical practice at all levels lags behind these ethical expressions of the duty to treat pain.

II. PHYSICIAN FAILURES TO TREAT PAIN: TORT AS A BEACON

A. Functions of tort liability

The rules developed by courts in malpractice suits serve a range of functions in altering medical practice. First, tort rules reinforce good medical practice. Case law is the voice of common law judges stating minimum principles of generally accepted medical practice. The cases typically defer to the medical consensus on a standard of practice without much judicial scrutiny of the standard. But case law is still an influencing force on medical practice nonetheless, as it imposes financial burdens on providers and their malpractice insurers for medical errors, ignorance of good practice, and tolerance of sloppy practice. A lawsuit inflicts a price on providers in insurance costs and defense costs. Providers, as consumers of lawyers and insurance, are at least somewhat sensitive to increases in price, heightening their sensitivity to bright-line rules of practice.

Second, tort rules give voice to patients who have been patronized, ignored, actively manipulated, or cruelly treated by physicians. Informed-consent doctrine has forced medical recognition of patients' informational needs; EMTALA has forced stabilizing treatment by hospitals inclined to simply push patients out the door; disclosure obligations have built on the physician's fiduciary duty toward patients.

Third, malpractice litigation drives institutional practices toward convergence on validated standards of practice. Lawyers can introduce evidence of emerging clinical practice guidelines as a way of arguing for a standard of care that the defendant failed to satisfy. Proof of malpractice thus slowly moves from elastic expert opinion toward more empirically validated clinical practices. This means that the defense has less wiggle room in the average malpractice case and, as a result, the law indirectly forces physicians toward heightened awareness of standards.

Fourth, tort law often articulates new duties of care for providers. Physicians not only must pay attention to emerging practices, but must also disclose risks to third parties created by a patient, candidly make a referral to a more skilled specialist, be honest with the patient, and watch out for the patient's interests over those of the provider. These new duties force providers to focus on the patient as primary.

These tort functions have implications for improving pain management. We have come to expect providers to master these new roles: provider of full information to patients as consumers of health care; protector of public health, through obligations to warn family members and third parties; stabilizer of patients even without a contractual relationship; and comforter and counselor of families. But current incentives in the health-care system push powerfully toward physicians' undertreating pain. As Ann Martino writes:

> [S]trong rewards, both internal and external to the practice of chronic pain management, reinforce the principle in the ethic of under prescribing to say no. A practitioner who accepts that addiction is harmful and that assisting or hastening death is a wrong has a duty to prescribe drugs in a manner that will not result in either. Federal and state prescribing laws, societal norms about the dangers of drugs, and board rules and regulations reward practitioners who under prescribe by making saying yes a risky proposition -- to practitioners' livelihood, reputation, and status in the practice community and under the law.[31]

The threat of malpractice litigation may offset these powerful forces, making anxious providers either overestimate the risk of suit or at least adjust their practice to a new assessment of the risk of suit. Surprisingly, most patients do not file a malpractice claim because of uncertainty as to the cause of their injury.[32] This is true even though studies of medical error have concluded that "the burden of iatrogenic injury is large enduring, and an innate feature of hospital care in the United States."[33] Even for patients with major permanent injuries, it appears that only about one in six file suit.[34] However, the threat of tort litigation has a substantial psychological impact on physicians in excess of the diluted financial incentives created.[35] Physicians overestimate the risk of being sued and the size of feared judgments.[36] The sheer unpleasantness of being sued also deters, although it has been argued that the lack of clarity as to the locus of negligence in most cases does not provide useful feedback to providers.[37]

Physicians clearly perceive a threat from the system, judging their risk of being sued as much higher than it actually is. The Harvard New York Study, surveying New York physicians, found that physicians who had been sued were more likely to explain risks to patients, to restrict their scope of practice, and to order more tests and procedures.[38] Malpractice insurers, particularly the physician-owned companies in many states, now engage in aggressive review of claims. These companies insure about 40 percent of physicians in active patient care. They routinely use physicians to review applications for insurance and to review the competence of those sued. Physicians with claims due to negligence, as assessed by the peer reviews, may be terminated, surcharged, or have

restrictions on their practice imposed.[39] If a physician loses his malpractice insurance, he may quit, switch jobs, or go without insurance. He may also go to a surplus-lines insurance company that charges much higher premiums for coverage. Claims exposure can thus lead to a direct financial impact on the physician who is forced to carry such expensive insurance.[40]

The litigation process is neither as arbitrary nor as unfair as critics suggest.[41] The jury turns out to be a surprisingly reliable decision-making institution.[42] Lawyers are good screens for frivolous cases. A physician named as a defendant may, as a consequence, spend more time on exams or patient histories, invest in further training, increase support staff, or develop a more systematic approach to pain management. The few available studies have found that physicians who have been malpractice defendants often alter their practice as a result, even if they win the litigation. Perceived risk is thus important to physician conduct.[43] Hospitals have instituted risk management offices and quality assurance programs; informed-consent forms have become ubiquitous; medical record-keeping with an eye toward establishing proof of care at trial has become the rule. There is little doubt that the threat of malpractice litigation has had some effect on provider practices, and that increases in litigation over inadequate pain management would likely spur improvements at the individual provider and institutional levels.[44]

B. The general malpractice rule

1. National standards of care

A liability analysis of pain management starts with the physician, since it is the physician who fails to prescribe proper medication or to assess and manage patient pain. The liability of physicians is governed by general medical malpractice principles. Malpractice is usually defined as unskillful practice resulting in injury to the patient, which constitutes a failure to exercise the "required degree of care, skill and diligence" under the circumstances.[45] A physician is not a guarantor of good results, nor is he or she required to exercise the highest degree of care possible. As one court said, "The physician will not be held to a standard of perfection nor evaluated with benefit of hindsight."[46]

The standard of care by which most state courts measure the conduct of both general practitioners and specialists is a national standard. A good statement of this standard is found in *Hall v. Hilbun*:

> The duty of care ... takes two forms: (a) a duty to render a quality of care consonant with the level of medical and practical knowledge the physician may reasonably be expected to possess and the medical judgment he may be expected to exercise, and (b) a duty based upon the adept use of such medical facilities, services, equipment and options as are reasonably available.[47]

Most jurisdictions impose a national standard of care on physicians[48] because of concerns about a "conspiracy of silence,"[49] unfair limitations on the use of experts, and a recognition of the national character of medical education and practice.[50] Nonetheless, many jurisdictions allow evidence describing the practice limitations under which the defendant labors.[51] Some jurisdictions explicitly allow the trier of fact to consider the facilities, staff, and other equipment available to the practitioner in the institution where he or she is affiliated. This follows the general rule that courts should take into account the locality, proximity of specialists, and special facilities for diagnosis and treatment.[52] The standard of care governs a physician's conduct during the period when the patient was under his or her care; this includes follow-up care to ensure that a patient obtains medical records and information as requested.[53]

Proving negligent pain management is difficult for the plaintiff in light of contemporary failures by the medical profession to practice pain management practices. Traditionally, tort law has allowed the medical profession to set the standards of practice, with the courts enforcing these standards in tort suits. Defendants trying to prove a standard of care normally present expert testimony describing the actual pattern of medical practice, historically without any reference to the effectiveness of that practice. Most jurisdictions give professional medical standards conclusive weight, so that the trier of fact is not allowed to reject the practice as improper.[54] On rare occasions, the courts have allowed the case to proceed in spite of agreement that the defendant satisfied the customary practice of his or her specialty because evidence was presented that the defendant was aware of the dangers in the standard practice.[55] Other more recent decisions have found that proof of "ordinary care" can prevail over a defense of compliance with custom.[56]

The standard of care is not usually a bright-line rule. The standard in Hall for judging the defendant's conduct was "minimally competent physicians in the same specialty."[57] This minimal competence test seems less demanding than standard jury instructions in other states that require comparison to "the average practitioner in the class to which he or she belongs."[58] "Average" suggests a midpoint in the range of practitioners, while "minimal" places the defendant's conduct distinctly lower on a scale of practice. The standard of care must be at least in compliance with available technology at the time the diagnosis or treatment was offered to the patient, without the benefit of hindsight.[59] So the issue of what is known by a "minimally competent" practitioner, held to a national standard and assuming up-to-date education, is a classic jury question, leaving the trier of fact to resolve the dispute among sparring experts from either side.

a. Clinical practice guidelines

What a minimally competent practitioner must know has not traditionally been derived from an external authority, such as a government standard, but rather from medical standards developed through the interaction of leaders in the profession, professional journals and meetings, and networks of colleagues. Most clinical policies develop from an ongoing exchange in the literature, at meetings, and in peer discussions. Over a period of time, a clinical policy takes shape from this series of interactions. If it becomes generally accepted, it becomes "standard practice."[60]

The development and proliferation of clinical practice guidelines has speeded the process by which good evidence-based medical practice becomes recognized and disseminated as such. In response to the rapid growth in medical research and published findings, these guidelines have become one of the transforming forces in current medical practice.[61]

Medical knowledge about evidence-based medicine has accumulated at a staggering rate. Between 1966 and 1995, the number of clinical research articles based on randomized clinical trials jumped from about 100 to 10,000 per year.[62] American physicians and specialty groups have expended substantial effort on standard-setting in recent years, specifying treatments for particular diseases. Clinical practice protocols (also referred to as practice parameters or guidelines[63]) have been developed by specialty societies such as the American Academy of Pediatrics; by the government, through the National Institutes of Health; and by individual hospitals in the clinical setting.

The development of practice standards and guidelines by national medical organizations has accelerated the process of moving all medical practice toward national standards.[64] Such guidelines provide a particularized source of standards against which to judge the conduct of the defendant physician, and the fact that they are produced by national medical specialty societies and the government means that they will be influential.[65]

Such guidelines are sets of suggestions, described in decision rules, based on current medical consensus about how to treat a certain illness or condition. The Institute of Medicine has defined clinical guidelines as "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances." They are standardized specifications for using a procedure or managing a particular clinical problem. Such guidelines may be quality-oriented, reducing variations in practice while improving patient care;[66] they may also be cost-reducing, promoting a lower cost approach to care.

A clinical standard may be presumptive evidence of due care if expert testimony introduces the standard and establishes its sources and its relevancy.[67] The guidelines can also be used to impeach the opinion of a medical expert.[68] Clinical guidelines potentially offer an authoritative and settled statement of what the standard of care should be for a given treatment or illness. A court has several choices when such guidelines are offered into evidence. A guideline might be evidence of the customary practice in the medical profession. A doctor practicing in conformity with a guideline would be shielded from liability to the same extent as one who can establish that she or he followed professional custom. A guideline could also serve as a defense to a claim that the defendant deviated from customary practice, insofar as it represents the practice of at least a "respectable" minority of the relevant profession.[69] The guideline acts like an authoritative expert witness or a well-accepted review article. Using guidelines as evidence of professional custom, however, is problematic if they are ahead of prevailing medical practice.

Guidelines have already had an effect on settlement patterns, according to surveys of malpractice lawyers.[70] Plaintiffs have used such guidelines to their advantage in malpractice cases, particularly the guidelines of the

American College of Obstetricians and Gynecologists.[71] Such guidelines provide a particularized source of standards against which to judge the conduct of the defendant physician. A widely accepted clinical standard may be presumptive evidence of due care, but expert testimony would still be required to introduce the standard and establish its source and relevancy. A guideline could thus be treated as negligence per se or at least a rebuttable presumption, which could then be countered with evidence.

Standards of care for pain management are increasingly well-established. Organizations such as the Agency for Health Care Policy and Research, the Agency for Healthcare Research and Quality, the American Pain Society, the American Academy of Pain Medicine, the American Geriatric Society, and the American Society of Anesthesiologists have promulgated pain control standards.[72] The Joint Commission on Accreditation of Healthcare Organizations and the National Committee on Quality Assurance have also been paying more attention to an institution's standards for pain management during the accreditation process.[73]

The use of such guidelines in pain management litigation is therefore likely. Consider the Practice Guidelines of the American Society of Anesthesiologists.[74] These guidelines develop an interrelated set of approaches to proper pain management, with several levels: a comprehensive evaluation and treatment plan (history, physical examination, psychosocial evaluation, impression and differential diagnosis, and treatment plan); a diagnostic evaluation; counseling and coordination of care; periodic monitoring and measurement of clinical outcomes; and multidisciplinary, multimodal pain management. Multimodal therapy is "concomitant use of separate therapeutic interventions under the direction of a single practitioner to obtain additive beneficial effects or reduction of adverse effects." These interventions might include neural blockade with medications, rehabilitative therapies with neural blockade, and medications of varying strengths.

Pain management guidelines demand at least an initial diagnostic assessment of pain as a clear starting point and then attention to following the patient and using pain management strategies in a well-established hierarchical fashion. For physicians who work in hospital settings or depend on managed care organizations for the bulk of their patients, knowledge of and compliance with guidelines will become a necessity. The guidelines provide the beginning of a bright-line test for measuring provider shortcomings in managing patient pain.

b. Web-based databases

The second force that reinforces the power of clinical practice guidelines is their easy availability on a range of Web sites.[75] Web sites have proliferated to help physicians gain efficient and user-friendly access to this even-greater proliferation of guidelines and other medical information.[76]

The National Guideline Clearinghouse[77] is the best example of this; it offers free access to physicians and others to the current clinical practice guidelines, with instantaneous searches of the database. A search produces all guidelines on a given subject, along with an "appropriateness" analysis for each guideline.[78] The Clearinghouse also provides a standardized abstract of each guideline, and grades the scientific basis of its recommendations and the development process for each. Full text or links to sites with the guidelines are provided. Readers are given synopses to produce a side-by-side comparison of guidelines, outlining where the different sources of guidelines agree and disagree. Physicians can access electronic mail groups to discuss development and implementation.

To be included on the Web site, these guidelines must pass certain entry criteria: They must be current; contain systematically developed statements to guide physician decisions; have been produced by a medical or other professional group, government agency, health-care organization, or other private or public organization; and show that they were developed through a systematic search of peer-reviewed scientific evidence. The benefits of such a database are apparent. It has search features, comprehensiveness, and easy access through its Internet location, making it the most powerful tool for using guidelines to date.[79]

Clinical practice guidelines have the power to influence the finding of a standard of care in a malpractice case, but are often ignored by busy physicians.[80] Physician adherence to guidelines appears to be hindered by inertia, lack of awareness, and external barriers, such as lack of time or difficulty of use.[81] As Stephen Lande writes: "The reality of the system ... is that physicians will resist attempts to change treatment practices and will ultimately revert to their own way of thinking except when they are explicitly pressured."[82] Physicians who work within managed care systems, as most do today, need to have reminder and feedback systems in place to reinforce their attention to guidelines.

Resistance to pain management practices combines these forces of inertia with the provider's additional fears about the extensive regulation of powerful opioids. However, Internet access to such guidelines in a quick and user-friendly way may hurry along the process of awareness and adoption of such guidelines and increase physicians' comfort level with better pain management practices. The location of current information on the Internet facilitates access for anyone with a computer, and the fact that the guidelines are linked to other commercial sites makes them easy to find, no matter what portal a physician uses to access medical information databases on the Web.[83]

With the rapid clinical deployment of personal digital assistants (PDAs), which can download material from the Internet and store volumes of clinical reference information, physicians will be expected to be familiar with the appropriate clinical guidelines for the patients they treat. One company, docuCare, now offers a handheld device to document patient care at the bedside -- to record vital signs, medications, the physician's pain assessment, and the patient's responses to a pain satisfaction survey.[84] The fact that a pain assessment survey is included with the device should emphasize to physicians the standard nature of taking such a survey.

A provider's failure to access medical databases like the National Guideline Clearinghouse is likely to become an important piece of evidence in a malpractice suit, since it is evidence that a physician failed to stay current in his or her field of practice. A physician who displays ignorance of current treatment guidelines may be attacked by the plaintiff using the results of a computer search to display these guidelines and their relative ease of access.[85] Refusal to listen to a patient's description of pain or to move to more effective drugs as needed, following the World Health Organization treatment pyramid or the pain management guidelines of various specialty organizations, will not be excused because of a claim that customary practice does not require it.

2. Other reasons to conform to the standard of care

A spectrum of liability doctrines are potentially available in situations where pain management is not given or is substandard.[86] The theoretical underpinning of all such theories is the same: failure to be aware of the standard of care for proper pain management or failure to conform to it.

The heart of any malpractice case is proof by the plaintiff that the defendant failed to meet the standard of care. If the physician provides pain management for a patient, it must be done properly. A claim for a failure to treat for pain is dependent on evidence that the standard of care requires proper pain management in the situation experienced by the plaintiff. A patient can expect proper treatment, defined by the emerging standards of care as encompassing a right to relief from pain.[87]

Can a physician argue defensively that he or she was not trained in medical school as to proper pain management and that the customary practice among physicians is to undertreat pain? If a customary practice is a nonreflective and uninformed practice, it may be attacked by the plaintiff's experts. A growing body of testimony by physicians who have studied pain reflects a growing consensus on the proper treatment of pain -- and you can bet that a plaintiff's pain is something about which every jury can understand and empathize.[88]

The issue is whether the customary practice is a reflective one or the result of ignorance and inertia. Modern case law has at times instructed the trier of fact that customary practice need not always be an absolute defense -- that evidence of good practice may be introduced. Judicial deference to customary practice is, in fact, weakening. The Wisconsin Supreme Court observed in *Nowatske v. Oserhoh*:[89]

> should customary medical practice fail to keep pace with developments and advances in medical science, adherence to custom might constitute a failure to exercise ordinary care.... [W]hile evidence of the usual and customary conduct of others under similar circumstances is ordinarily relevant and admissible as an indication of what is reasonably prudent, customary conduct is not dispositive and cannot overcome the requirement that physicians exercise ordinary care.

The respectable minority defense allows a physician who wants to follow pain management guidelines to defend his or her practice in the face of a different customary practice. Pain management guidelines are already generally accepted and used as a reference in workers compensation cases in many states, since workers often claim both job-related disability and the pain that results from that disability.[90] The workers compensation judge often has to make findings as to whether a particular medical treatment is necessary. Statutes clearly allow compensation not only for curative treatment but also for palliative treatment, including aggressive pain management using opioids long term.